U.S. Department of Justice
Drug Enforcement Administration

ARCOS REGISTRANT HANDBOOK

Office of Diversion Control

Version 1.0 August 1997

ARCOS REGISTRANT HANDBOOK

SUMMARY OF REPORTING CHANGES

- **Transaction Code is new. Transaction Codes 5, R, and V have new meanings.**

- **Transaction date can be outside the period covered when a transaction is identified as a late (insertion), deletion, or adjustment transaction or when a correction number is entered.**

- **The Lot Number field has been replaced by the correction number field.**

- **The Submission Control form has been eliminated and replaced by the bar code label.**

- **Delete Indicator has been renamed "Action Indicator." The permissible entries in the Action Indicator field are D, A, and I.**

- **Mixed media reporting, automated and manual, is no longer accepted. Corrections must be included with regular monthly or quarterly reports rather than being submitted separately.**

DRUG ENFORCEMENT ADMINISTRATION
OFFICE OF DIVERSION CONTROL
DRUG OPERATIONS SECTION
ARCOS UNIT

Notice: This contact information has been updated as of February 2000

CONTACT INFORMATION

MAILING ADDRESS

Drug Enforcement Administration
ARCOS Unit
P. O. Box 27273
Washington, D.C. 20038-7273

Courier Service/Overnight Mailing Address
Drug Enforcement Administration (DEA) Headquarters
ATTN: ARCOS Unit
2401 Jefferson –Davis Highway
Alexandria, VA 22301

Office Voice Phone Number:
(202) 307-8600 Hours: Monday - Friday 8:30 a.m. - 5:00 p.m. EST/EDT

Office Fax Phone Number:
(202) 307-8612 Hours: 7 days/week 24 hours/day

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SECTION 1.0

ARCOS OVERVIEW

1.1 WHAT IS ARCOS?

1.1.1 ARCOS Defined

The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispensing (consumption) level.

1.1.2 Authority for ARCOS

Manufacturers and distributors ***must*** periodically report to DEA (ARCOS) their inventories of selected controlled substances and increases and decreases to the inventories of these substances. Reporting is mandated under the Code of Federal Regulations (CFR), 21 CFR 1304. A copy of the CFR can be purchased from the Government Printing Office. The address and phone number are:

U.S. Government Printing Office
Superintendent of Documents, Mail Stop: SSOP
Washington, D.C. 20402-9328

Phone: (202) 512-1800

1.2 ARCOS' RELATIONSHIP TO DRUG INVENTORY AUDIT

DEA has the capability to perform analyses on filled order form data (DEA Form 222), since ARCOS captures and stores this information. This increases the federal government's ability to detect potential diversion situations.

1.3 ARCOS' RELATIONSHIP TO UNITED NATIONS

DEA is responsible for fulfilling United Nations' treaty obligations which relate to the international control of certain narcotic drugs and psychotropic substances. ARCOS software provides automated consumption, manufacturing, and inventory data which serve as a basis for establishing the United States' estimates of medical and scientific needs and the establishment and maintenance of inventories. The United States submits these estimates annually to the United Nations' International Narcotics Control Board (INCB), in Vienna, Austria. The INCB uses the United States' estimates to determine worldwide estimates.

DEA also sets annual manufacturing and procurement quotas for Schedules I and II controlled substances under the United States Controlled Substances Act. These quotas cannot be exceeded during the calendar year for which they are given. DEA submits annually to the INCB statistics on the United States' consumption, manufacturing, and year-end inventories of the narcotic drugs and psychotropic substances which are controlled under the 1961 and 1971 Conventions.

1.4 REPORTING: WHO and WHAT

Manufacturers and distributors are required to report controlled substance inventories and transactions as follows:

a. Manufacturers of bulk and/or dosage form controlled substances

- *Inventories*
  - All controlled substances in Schedules I and II
  - All narcotic controlled substances in Schedule III
  - Selected psychotropic controlled substances in Schedules III and IV (see list in Section 6, Manufacturing Activities)
- *Acquisitions*
  - All controlled substances in Schedules I and II

- All narcotic controlled substances in Schedule III

- *Dispositions*
  - All controlled substances in Schedules I and II
  - All narcotic controlled substances in Schedule III
- *Manufacturing Activities*
  - All controlled substances in Schedules I and II
  - All narcotic controlled substances in Schedules III
  - Selected psychotropic controlled substances in Schedules III and IV (see list in Section 6, Manufacturing Activities)

b. Manufacturers that ***only*** label, relabel, package, or repackage controlled substances

- All controlled substances in Schedules I and II
- All narcotic controlled substances in Schedule III

c. Distributors of bulk and/or dosage form controlled substances

- All controlled substances in Schedules I and II
- All narcotic controlled substances in Schedule III

1.4.1 Submitting Report

DEA recommends that each ARCOS report be sent by United States Postal Service certified mail, along with a return receipt requested card, PS Form 3811, December 1994 (green card). Irrespective of the delivery method, DEA (ARCOS) ***must*** receive the report by the 15th day of the month following the close of the reporting period. Otherwise, your company could appear in a delinquent reporting status. If time constraints dictate a faster delivery method, overnight mail or a courier service may be used. Both the normal mailing address for DEA and the address for courier or overnight mail are located on the contact information page at the front of this handbook. Exhibit 1.1: Receipt Deadlines, illustrates the deadlines by which DEA (ARCOS) ***must*** receive the monthly or quarterly

ARCOS reports.

SAMPLE DEA RECEIPT DEADLINES FOR ARCOS REPORTS

Reporting Period End	Reporting Frequency	Reporting Deadline
February 28th	Monthly	March 15th
September 30th	Monthly	October 15th
September 30th	Quarterly	October 15th

Exhibit 1.1: Receipt Deadlines

1.5 WHO MUST *NOT* REPORT?

Individuals, firms, or institutions that hold a DEA registration and are listed in Exhibit 1.2: Registrants ***Not*** Required to Report, ***must not*** report to DEA (ARCOS) their controlled substance inventories or transactions.

WHO MUST NOT REPORT TO ARCOS?
Practitioners
Pharmacies
Hospitals or Clinics
Teaching Institutions
Analytical Laboratories
Researchers
Narcotic Treatment Programs
Importers
Exporters

Exhibit 1.2: Registrants *Not* Required to Report

1.6 MULTIPLE REGISTRATIONS

DEA issues a ***separate*** registration to manufacturers and distributors of controlled substances for ***each*** location in which controlled substance activity occurs. Therefore, manufacturers and distributors may hold multiple registrations ***simultaneously***. Each individual registration is identified by a unique registration number. Those firms holding multiple registrations need to make certain that the DEA registration number (*reporting registrant number*) used in reporting controlled substance transactions ***corresponds*** to the location where the activity occurred.

If a firm holds a DEA registration as a manufacturer and/or distributor of controlled substances and, in addition, holds a registration as an enterprise listed in Section 1.5, Who Must Not Report, the firm is ***only*** required to report to DEA (ARCOS) controlled substance transactions and inventories that pertain to its registration as a manufacturer and/or distributor.

Example:

A firm holds a registration as an importer of controlled substances and ***simultaneously*** holds a second registration as a distributor of controlled substances. Only the inventories and transactions of the distributor are reportable to DEA (ARCOS). Additionally, when reporting the distributor's inventories and transactions, the firm ***must*** be certain to use ***only*** the distributor's registration number as the reporting number.

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SECTION 2.0

REPORTING REQUIREMENTS

2.1 GENERAL REPORTING REQUIREMENTS

Manufacturers and distributors are required to report their annual inventories of specific controlled substances and increases and decreases in these inventories to DEA (ARCOS). The CFR requires that an ***annual*** inventory of each reportable controlled substance be taken on December 31st of each year and filed with DEA (ARCOS) ***no later than January 15th*** of the following year. *Increases and decreases* in the inventory of ***each*** reportable controlled substance ***must*** be reported on a monthly or quarterly basis and filed with DEA (ARCOS) ***no later than the 15th of the month*** following the end of the reporting period.

2.2 RETAINING COPIES

A copy of each ARCOS report submitted to DEA ***must*** be kept for two (2) years after the last day of the reporting period. ARCOS output such as error listings, delinquency letters, etc. ***must*** also be kept for two (2) years.

2.3 REPORTING MEDIA

ARCOS reports may be submitted on magnetic diskette, magnetic tape or cartridge, or DEA Form 333. Each registrant may select the reporting media which is best suited to its organization. However, data reported on magnetic media will generate fewer errors than data manually coded on DEA Form 333. Detailed instructions concerning the use of each of these media for ARCOS reports are given in Section 3, Reporting Media.

2.4 REPORTING FREQUENCY

ARCOS registrants may choose ***either*** a monthly or a quarterly reporting frequency. The reporting frequency must be the ***same*** for a central reporter and ***all*** of its subsidiaries. Those registrants wishing to change their reporting frequency ***must*** obtain ***written*** authorization from DEA (ARCOS) ***before*** submitting reports according to the new frequency. A written request to change the reporting frequency ***must*** be submitted on company letterhead and may be sent by mail or fax to the Data Systems Unit (ARCOS). The address and fax phone number are located on the contact information page at the front of this handbook.

2.5 TRANSMITTAL INFORMATION

The Submission Control Form is no longer required. It has been replaced by a bar code label. See Section 3, Reporting Media, for bar code label instructions.

2.6 ARCOS REGISTRANTS AND REPORTERS

An ARCOS registrant is a manufacturer or distributor required to report controlled substance inventories and transactions to DEA (ARCOS). An ARCOS reporter is an entity that files controlled substance transaction and inventory reports with DEA (ARCOS). A reporter may or may not hold a DEA registration. There are three types of ARCOS reporters: (1) single reporters, (2) registered central reporters, and (3) non-registered central reporters.

2.6.1 Single Reporter

An ARCOS registrant reporting ***only its own*** controlled substance transactions and inventories to DEA (ARCOS) is a single reporter. If an ARCOS registrant is a subsidiary of a larger corporate entity and submits its own ARCOS reports, it ***must*** follow the instructions for a ***single reporter***.

2.6.2 Registered Central Reporter

A registered central reporter ***has*** a DEA registration as a manufacturer or distributor and reports controlled substance transactions and inventories for ***itself and other*** ARCOS registrants within its corporate structure.

2.6.3 Non-registered Central Reporter

A non-registered central reporter ***neither*** manufactures ***nor*** distributes controlled substances, ***does not*** have a DEA registration, and ***does not*** have controlled substance transactions or inventories, ***but reports*** the controlled substance transactions and inventories of the ARCOS registrants within its corporate structure.

2.6.4 Pre-batch Central Reporter

The pre-batch central reporter became an ***obsolete category*** with the reporting period beginning January 1, 1997. Beginning with the first reporting period in calendar year 1997, a *control record* replaced the batch header card. On January 1, 1997 each former pre-batch central reporter became either a registered central reporter or a non-registered central reporter.

2.7 CENTRAL REPORTING

An ARCOS registrant may submit reports for one or more of its registered locations by obtaining a central reporting identifier number from DEA (ARCOS). This number constitutes authorization from DEA (ARCOS) to report from a central location. The central reporting identifier number is used for internal control by the Data Systems Unit (ARCOS) only.

2.7.1 Applying

A written request for authorization to submit ARCOS reports from a central location ***must*** be

sent to the Data Systems Unit (ARCOS) on company letterhead. Mail or fax the request to the address or fax phone number listed on the contact information page at the front of this handbook. Each request ***must*** contain the following information:

a. Name of the firm responsible for central reporting.

b. DEA registration number of the firm responsible for central reporting, if any. Reports can be submitted centrally from a non-registered location.

c. Address of the central reporting location. All mail will be returned to the central location ***unless*** DEA is given written instructions to send correspondence to each reporting address.

d. Name, DEA registration number, and address of each location for which reports will be submitted from the central location.

e. Name and telephone number of the individual at the central reporting location to contact regarding any ARCOS reporting problems.

2.7.2 Issuing

The Data Systems Unit (ARCOS) needs approximately one (1) month to issue a central reporting identifier number. Your firm will be notified once the number has been issued. Do ***not*** submit any ARCOS reports as a central reporter until you have received the central reporting identifier number.

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SECTION 3.0

REPORTING MEDIA

3.1 REPORTING MEDIA TYPES

ARCOS registrants may report controlled substance transactions by using DEA Form 333 (manual reporting) or by using a magnetic tape reel, magnetic diskette, or magnetic tape cartridge (automated reporting). Both methods report the same information in slightly different formats. DEA supplies Form 333 to ARCOS registrants employing the manual reporting method. Those registrants reporting on magnetic media must supply their own tape reels, tape cartridges, or diskettes. DEA returns magnetic media, but does ***not*** return Form 333.

DEA ***strongly encourages*** ARCOS registrants to submit their reports on magnetic media to facilitate timely and accurate processing. ***Each*** ARCOS report, whether submitted on DEA Form 333 or magnetic media, ***must*** have a bar code label.

3.2 CONFORMING TO SPECIFICATIONS

Media which do not conform to the specifications in this section will be returned unprocessed. ***Failure to submit ARCOS reports on time and on media which adheres to these specifications could result in your firm appearing in a delinquent reporting status.***

3.3 LABELING MEDIA

The Data Systems Unit (ARCOS) uses a bar code labeling system to track ARCOS reporting media. The bar code label replaces the Submission Control Form and all external labels that have been used previously. Exhibit 3.1: ARCOS Bar Code Label, illustrates this new label. The labels contain each ARCOS registrant's DEA registration number and the first 20 characters of the company's name. ***Non-registered central reporters*** have been assigned a pseudo-registration number ***for bar code use only***. The label also contains a 3-digit bar-coded identifying number which permits each piece of magnetic media or ***group*** of DEA Form 333 coding sheets to be uniquely identified. ***One label*** must be placed on ***each*** magnetic tape reel or cartridge and on each magnetic diskette submitted to DEA. For DEA Form 333 ***one label only*** must be placed on the ***first page*** of each ***group*** of forms. Specific instructions for applying the bar code label are included in the detailed discussions for each type of media.

DEA provides each ARCOS registrant with an initial supply of 18 self-adhesive, ARCOS bar code labels. When our records indicate that you have used 12 labels we will send more. If labels are lost or destroyed, additional labels may be ordered by telephone or fax from the Data Systems Unit (ARCOS). Voice p hone and fax phone numbers are located on the contact information page at the front of this handbook.

3.3.1 Completing Label

See Exhibit 3.1: ARCOS Bar Code Label, for the sample label.

"From" Block:

Write the month, first day and last two digits of the year for the ***beginning*** of the period covered by this ARCOS report.

Format: MMDDYY
EXAMPLE: April 1, 1997 is written as 040197.

"To" Block:

Write the month, last day and last two digits of the year for the ***ending*** of the period covered by this ARCOS report.

Format: MMDDYY
EXAMPLE: April 30, 1997 is written as 043097

“Note” Block -

Use this space to write any miscellaneous information about the ARCOS report you are submitting.

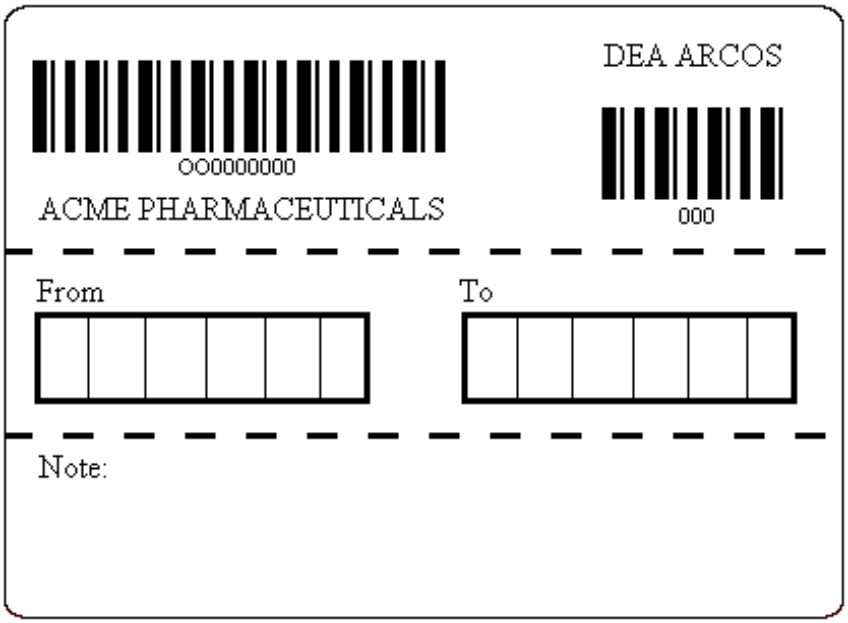

Exhibit 3.1: ARCOS Bar Code Label

3.4 PACKING MEDIA FOR MAILING

Media ***must*** be securely packed and wrapped to prevent damage while in transit to DEA (ARCOS).

3.5 QUESTIONS

Questions about reporting media may be directed to the Data Systems Unit (ARCOS) by letter, telephone, or fax. The address, phone number, and fax number are located on the contact information page at the front of this handbook.

3.6 MANUAL REPORTING

ARCOS registrants reporting manually ***must*** use DEA FORM 333. This form is a 2-part, 80-column coding sheet supplied by DEA (ARCOS). See Exhibit 3.2: DEA Form 333, for an illustration.

ARCOS TRANSACTION REPORTING

DRUG ENFORCEMENT ADMINISTRATION

MAILING INSTRUCTIONS

Retain duplicate for your records.
Mail the Original of completed form to:

Drug Enforcement Administration
ARCOS
P.O. Box 28293
Washington, D.C. 20038 - 8293

INSTRUCTIONS FOR CODING FORM

1. Characters should be printed neatly and conform as closely as possible to examples below.
2. All fields in the transaction (except the transaction code (Field 2) and the delete code (Field 3) are capable of being duplicated without coding the entire field to accomplish this. It is necessary that the first (leftmost) character in each field to be duplicated is coded using an equal (=) sign. The equal sign is the only character which can be used for this purpose.

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OMB Approval
No. 1117 - 0003

0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z * = ~~K L M~~

REPORTING REGISTRANT NUMBER	TRANSACTION CODE	DELETE CODE	NATIONAL DRUG CODE: LABELER CODE	NATIONAL DRUG CODE: PRODUCT CODE	NATIONAL DRUG CODE: PKG. CODE	QUANTITY - Nbr. of Packages, Volume or Weight	UNIT	ASSOCIATE REGISTRATION NUMBER	DEA ORDER FORM NUMBER	LOT NUMBER (DEA USE ONLY)	STRENGTH	TRANSACTION DATE: YR.*	TRANSACTION DATE: MO.	TRANSACTION DATE: DAY	TRANSACTION IDENTIFIER
FIELD 1	2	3	4			5	6	7	8	9	10	11	12	13	14

* Unit (Right) Digit of Transaction Year

DEA Form — 333
(Feb. 1991)

Previous editions may be used.

Exhibit 3.2: DEA Form 333

3.6.1 Additional Forms

ARCOS reports submitted on photocopies of DEA Form 333 will ***not*** be accepted. Registrants may order DEA Form 333 by: (1) telephone, (2) fax, or (3) including a *transaction code F* in their next monthly or quarterly ARCOS report. A maximum of 500 copies of DEA Form 333 may be ordered at any one time. See Section 5, Transaction Record for *transaction code F* instructions. Voice phone and fax phone numbers are located on the contact information page at the front of this handbook.

3.6.2 Entry of Data

DEA Form 333 ***must*** be completed in pencil ***only***. Forms completed in other than pencil will ***not*** be accepted. A number 2 or medium soft lead pencil should be used. Be sure that the pencil used leaves an impression which is easily read. ***Careful forming of letters and numbers will lessen the chance of errors.*** An example of how each alphabetic or numeric character must be written is printed at the top of the form. There ***must*** be no written comments on the DEA Form 333.

3.6.3 Page Numbering

3.6.3.1 Single Reporters

Each page of the ***manual*** ARCOS report must include the current, sequential page number and the total number of pages in the report. This information is recorded in the upper right-hand corner of DEA Form 333 in the spaces after the words ***"Page _____ of _____."*** A manual report which contains 28 separate pages will be numbered "Page 1 of 28," "Page 2 of 28," "Page 3 of 28 ," etc. Exhibit 3.3: DEA Form 333 Page Numbering, illustrates the numbering.

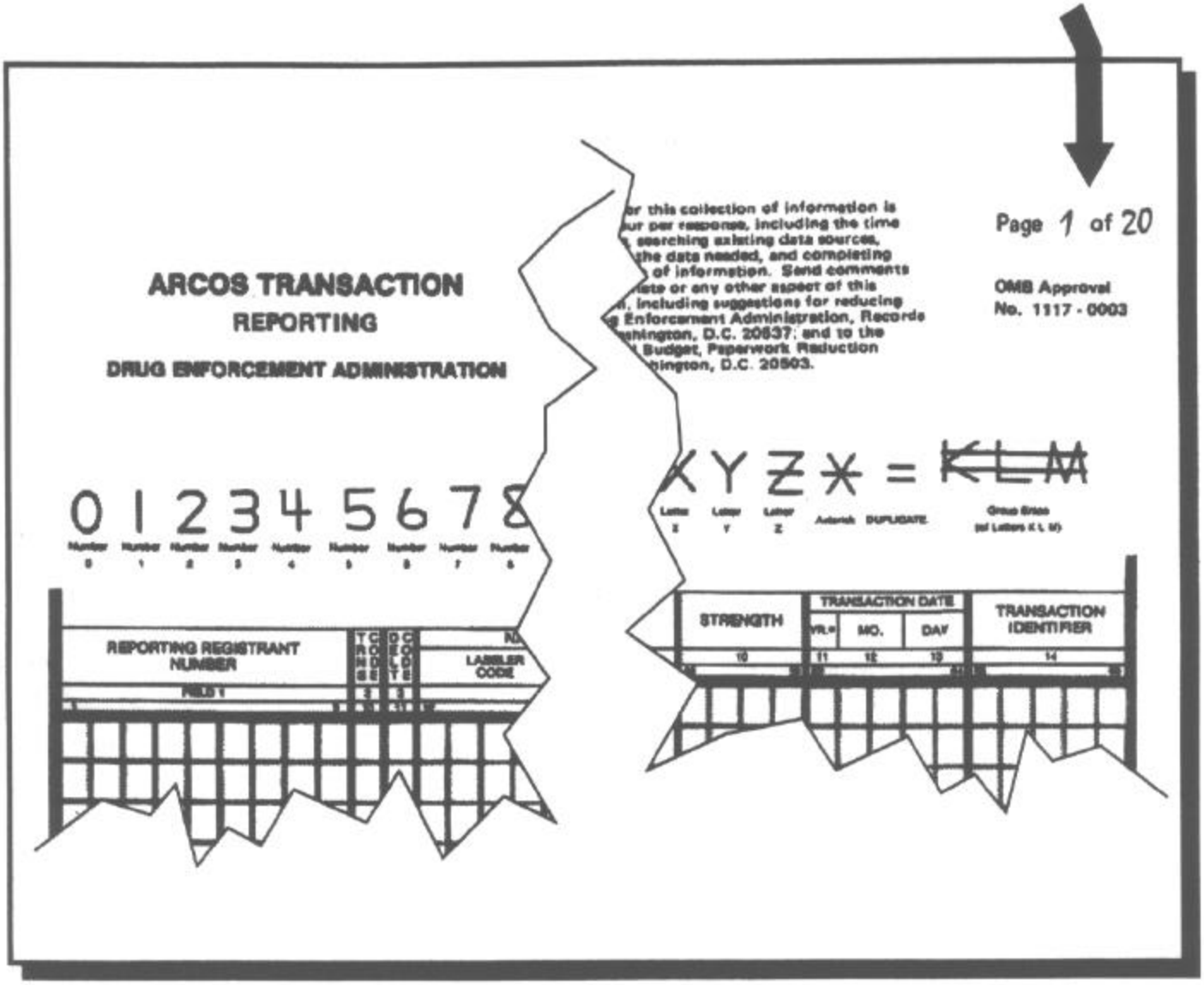

Exhibit 3.3: DEA Form 333 Page Numbering

3.6.3.2 Central Reporters

A central reporter ***must consecutively number*** all the pages of DEA Form 333 being submitted. This requirement applies to a central reporter submitting reports for itself and subsidiaries as well as to a central reporter submitting reports solely for its subsidiaries.

Example:

A central reporter submits three reports, the first report contains 15 pages, the second report contains five (5) pages, and the third report contains two (2) pages. The three reports have a total of 22 pages among them. Exhibit 3.4: Central Reporter Page Numbering, illustrates how these pages are to be numbered.

DEA Form 333 Page Numbering: **Central Reporter**

First Report:	"Page 1 of 22, Page 2 of 22...Page 15 of 22."
Second Report:	"Page 16 of 22, Page 17 of 22...Page 20 of 22."
Third Report:	"Page 21 of 22" and "Page 22 of 22."

Exhibit 3.4: Central Reporter Page Numbering

3.6.4 DEA Form 333: Applying Label

Each ARCOS report submitted on DEA Form 333 by a single reporter and ***each group*** of reports submitted by a central reporter ***must*** be identified by ***one, single*** bar code label. The label ***must*** be placed on the ***first page*** of each report or ***group*** of reports.

Example: Single Reporter

A single reporter submits a report containing 30 pages. One bar code label is placed on the ***first*** page of this 30-page report.

Example: Central Reporter

In Exhibit 3.4: Central Reporter Page Numbering, located on the previous page, the central reporter is submitting three reports. However, ***only one (1)*** label is required! This label is placed on the first page of this group of reports.

3.6.4.1 Label Placement

Exhibit 3.5: Positioning Label on DEA Form 333, located on the following page, illustrates the placement of the bar code label.

Place bar code label over the "Public reporting burden" paragraph on the first sheet of the group of coding sheets.

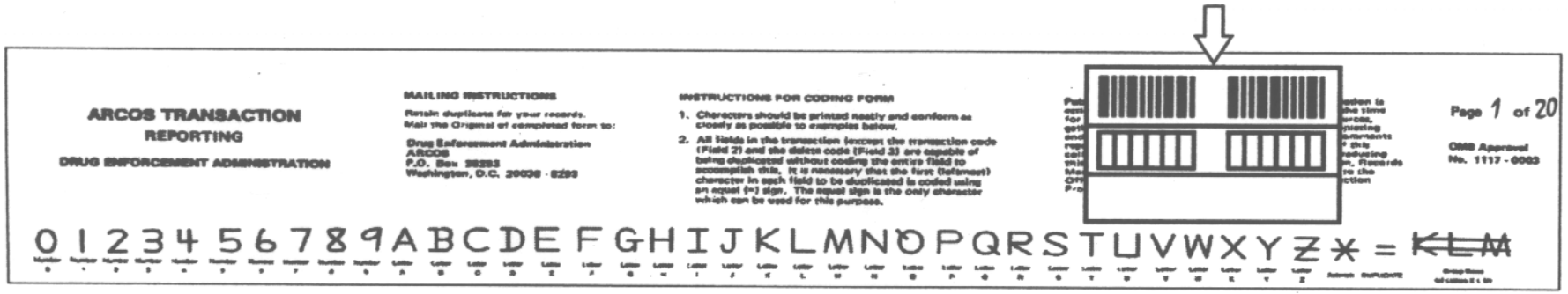

Exhibit 3.5: Positioning Label on DEA Form 333

3.6.5 Return of Unprocessable Forms

All ARCOS reports submitted on DEA FORM 333 will be reviewed prior to computer processing. A report that is illegible, incomplete, or incorrect will be returned unprocessed by certified mail, along with a letter of explanation.

3.7 MAGNETIC TAPE REPORTING

ARCOS reports may be submitted on reel or cartridge magnetic tape media. The following sections contain detailed specifications which ***must*** be met by ***all tape*** media being submitted to DEA (ARCOS).

3.7.1 Equipment Compatibility

DEA currently uses ***STC 3450*** or ***3650*** tape ***reel*** drives and the ***IBM 3490 D32XF*** tape ***cartridge*** drive. If ARCOS reports are submitted on magnetic ***tape*** media, the media ***must*** be compatible with this equipment.

3.7.2 Recording Tracks and Tape Width

Reports being submitted on ***round-reel tapes*** must be recorded on ½inch-wide mylar-based tape using a nine (9) track tape drive compatible with ***STC 3450*** or ***3650*** tape ***reel*** drives.

Reports being submitted on ***tape cartridges*** must be recorded on ½inch wide tape compatible with the ***IBM 3490*** tape ***cartridge*** drive.

3.7.3 Recording Density

All data ***must*** be recorded at either 1600 or 6250 bytes per inch (BPI).

3.7.4 Data Representation

All data ***must*** be recorded in IBM EBCDIC code.

3.7.5 Internal Tape Labels

All tapes ***must*** be created as ***non-labeled*** tapes. Tapes containing internal header labels are ***not*** acceptable.

3.7.6 Leading Tape Marks

There ***must*** be ***no tape mark(s)*** between the beginning of the tape reflective strip and the first data record on the tape.

3.7.7 Record Length

All *control* and *transaction records* ***must*** be fixed, eighty (80) characters in length.

3.7.8 Block Length

Data blocks ***must*** be fixed in length. Records ***must*** be blocked at:

a. One (1) record per block (80 characters per block) or
b. 20 records per block (1600 characters per block)

3.7.9 End of Data Tape Mark

The last block of records ***must*** be followed by at least one (1) tape mark to indicate the end-of-file (EOF) condition.

3.7.10 Tape: Applying Label

Each submitted magnetic tape, whether reel or cartridge, ***must*** have the bar code label supplied by DEA (ARCOS). This is the only required label and it replaces all other labels used previously. The label ***must*** be affixed to the tape reel or cartridge itself, ***not*** to the canister or outer container.

Remove any existing labels, including any prior bar code labels, before attaching the new bar code label. Place the label on the flat face of the tape reel or cartridge. If the label is too big for the face of the tape reel or cartridge, cut it along the dotted line(s) and place all the pieces on the flat face of the tape reel or cartridge. Smooth the label with a slight hand-pressure. Exhibit 3.6: Positioning Label on Magnetic Tape, illustrates the placement of the bar code label.

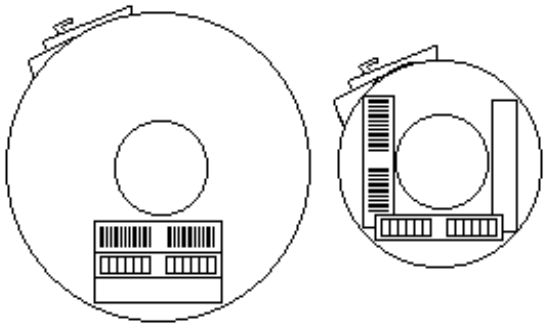

Exhibit 3.6: Positioning Label on Magnetic Tape

3.7.11 Return Of Magnetic Tapes

DEA will return magnetic tapes, both reel and cartridge, to ARCOS registrants by certified mail. If magnetic tapes cannot be processed, a letter of explanation will accompany unprocessed tapes.

3.8 MAGNETIC DISKETTE REPORTING

ARCOS reports may be submitted on magnetic diskette. To accommodate the variety of diskette devices that are in use, several standards regarding data recording, formatting, and file organization have been established.

3.8.1 Magnetic Diskette Types

ARCOS registrants submitting reports on diskettes ***must*** use magnetic diskette media that are either 3½inch or 5¼inch in diameter. Exhibit 3.7: Diskette Attributes, provides examples of magnetic diskette media that are available in the marketplace and their corresponding capacities and recording densities.

3½inch & 5¼inch MAGNETIC DISKETTE ATTRIBUTES

Type	Capacity	Diameter	Label Identification
Single-Sided	100 KB 160 KB 180 KB	5¼"	Single/single Single/double Single/double
Double-Sided	320 KB 360 KB	5¼"	Double/double DD, 40 Track, 48 TPI
High Capacity	1.2 MB	5¼"	HD, 80 Track, 96 TPI
Double-Sided	720 KB 1.44 KB 2.88 KB	3½	DD, 1MB, 2HC HD, 2MB HD, 4MB

Legend: MB (megabytes) = 1,024,000 bytes
KB (kilobytes) = 1,024 bytes

DD = Double density
HC = High capacity
HD = High density

Exhibit 3.7: Diskette Attributes

3.8.2 Compatibility Requirements

DEA recognizes that ARCOS registrants use a variety of hardware and software. However, DEA ***strongly encourages*** ARCOS registrants to use DOS-formatted magnetic diskettes. Reports submitted on diskette ***must*** meet the following:

a. Reports ***must not*** contain any data that has been compressed using data compression software,

b. Reports ***must*** be recorded using the American Standard Code for Information Interchange (ASCII) character set,

Note: Many software packages (e.g. word processing and spread sheet software) automatically save files in their own proprietary format.

ARCOS reports saved in a proprietary format ***must*** be converted to ASCII before being submitted to DEA (ARCOS).

c Records ***must*** have a ***fixed-length of 80-characters***,

d. There ***must*** be ***no delimiters*** between fields within records,

e. An ASCII line-feed/carriage return ***must*** be used to terminate each ***record***, and

f. "Ctrl-Z" (end-of-file marker) ***must*** be used to terminate each ***file***.

3.8.3 Magnetic Diskette Formatting

3.8.3.1 New Magnetic Diskettes

Each magnetic diskette ***must*** be initialized or formatted prior to its use.

3.8.3.2 Re-using Magnetic Diskettes

Previously used magnetic diskettes may be re-used, if they have been re-formatted. Reformatting ***must occur before*** the current ARCOS report is recorded. Re-formatting provides two specific benefits:

a. Re-formatting purges all existing data from the magnetic diskette, maximizing the recording capacity for ARCOS data.

b. The physical condition of the magnetic diskette is examined during re-formatting. Do ***not*** use magnetic diskettes with defective tracks, sectors, or allocation units.

3.8.4 File Name

"**L1ARCOS**" is the file name that ***must*** be assigned to each ARCOS report on magnetic diskette. Depending upon the software used to generate the file, either "**.TXT**" or "**.PRN**" may be automatically assigned as a file name extension. The ***only*** permissible file names for ARCOS reports on magnetic diskette are:

a. L1ARCOS
b. L1ARCOS.TXT
c. L1ARCOS.PRN

3.8.5 Total Transactions per Magnetic Diskette

The total number of individual ARCOS records on a single magnetic diskette ***must never*** exceed 85% of the magnetic diskette's formatted capacity or a maximum of 15,300 records. However, this limitation will vary depending upon the capacity of the specific magnetic diskette medium being used. Exhibit 3.8: Magnetic Diskette Limits, illustrates the maximum transactions for various sizes of magnetic diskettes. Exhibit 3.9: Limit Calculation, provides the formula used to calculate the limits.

ARCOS Record Limits for 3½ & 5¼" Magnetic Diskettes	
Maximum Capacity of Formatted Diskette	**Maximum Transactions**
320 KB (DOS, Single Sided, 5¼")	3,400
360 KB (DOS, Dual Density, 5¼")	3,825
400 KB (MAC)	4,250
720 KB (DOS, Dual Density, 3½)	7,650
800 KB (MAC)	8,500
1.2 MB (DOS, High Density, 5¼")	12,750
1.44 MB (DOS, High Density, 3½)	15,300

Exhibit 3.8: Magnetic Diskette Limits

Calculation of Magnetic Diskette Limits

maximum number of transactions = (maximum capacity of formatted magnetic diskette * 1000) * .85 / 80 bytes in a *transaction record*

Example:

Calculate the maximum transactions for a 5 1/4", single sided 320 KB DOS magnetic diskette

(320 * 1000) * .85 / 80 = 320,000

320,000 * .85 / 80 = 3,400 transactions

Note: The maximum capacity of a formatted magnetic diskette is approximate.

Exhibit 3.9: Limit Calculation

When a single ARCOS report file exceeds the record limit, it must be split into additional files. Each file must be submitted on a separate magnetic diskette. The *control record* will ***remain*** with the ***beginning*** of the report on the ***first*** magnetic diskette. That portion of the report being put on subsequent magnetic diskettes ***must only*** have *transaction records*. There ***must not*** be a *control record* on any subsequent magnetic diskette. The number of records on each magnetic diskette ***must*** be written in the "Notes" block of the bar code label.

Example:

A registrant's report contains 46,350 records submitted on 3½1.44MB diskettes. This report ***must*** be submitted on ***four*** of these diskettes, since each magnetic diskette is limited to 15,300 records, as follows:

Magnetic diskette number 1:	will contain the single ***control record*** plus 15,299 ***transaction records***, "15,300 records" is written in the "Notes" block of the bar code label,
Magnetic diskette number 2:	will contain ***only transaction records***, "15,300 records" is written in the "Notes" block of the bar code label,
Magnetic diskette number 3:	will also contain only ***transaction records***, "15,300 records" is written in the "Notes" block of the bar code label and,
Magnetic diskette number 4:	will contain the remainder of the ***transaction records*** (450), "450 records" is written in the "Notes" block of the bar code label.

3.8.6 Magnetic Diskette: Applying Label

Each submitted magnetic diskette ***must*** have the bar code label supplied by DEA (ARCOS). This is the only required label and it replaces all other labels used previously. The label ***must*** be affixed to the magnetic diskette itself, ***not*** to the cardboard envelope or any outer container. Remove any existing labels, including any prior bar code labels, before attaching the new bar code label. The following two exhibits, Exhibit 3.10: Label Position for 3½inch magnetic diskette and Exhibit 3.11: Label Position for 5¼inch magnetic diskette, illustrate the bar code label placement for these magnetic diskettes.

3½inch Magnetic diskette:

Place the label within the indented area on the front of the disk (see illustration below). Smooth out any wrinkles with gentle pressure. Do **NOT** cover any metal parts with the label.

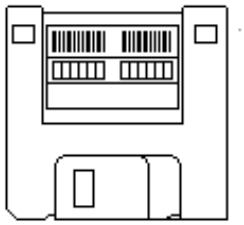

Exhibit 3.10: Label Position: 3½inch Magnetic Diskette

5¼inch Magnetic Diskette:

Wrap the label over the top of the disk by folding the label along the dotted line between the From/To Dates and the Note blocks as you apply it to the disk. This will put the printed label upside down on the front of the disk (see illustration below). Do **NOT** cover any of the exposed disk surfaces or the write protect notch located on the side of the disk. Smooth out any wrinkles with gentle pressure.

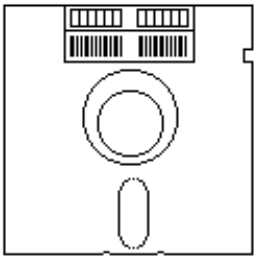

Exhibit 3.10: Label Position: 3½inch Magnetic Diskette

3.8.7 Return of Magnetic Diskettes

DEA will return magnetic diskettes to ARCOS registrants by certified mail. If a magnetic diskette cannot be processed, a form letter explaining the reason(s) for the magnetic diskette's return will accompany the unprocessed magnetic diskette.

PART II: REPORT PREPARATION

SECTION 4 CONTROL RECORD
SECTION 5 TRANSACTION RECORD
SECTION 6 MANUFACTURING ACTIVITIES

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INTRODUCTION TO PART II

Part II of the ARCOS Reporting Handbook covers the preparation of the ARCOS report and consists of three sections: Section 4, Control Record; Section 5, Transaction Record; and Section 6, Manufacturing Activities. These three sections discuss in detail ***what*** information to report and ***how*** to report it. Sections 4 and 5 apply to ***all*** registrants holding DEA registrations as ***manufacturers*** or ***distributors*** of reportable controlled substances. Section 6 applies ***only*** to those registrants conducting ***manufacturing activities*** in reportable controlled substances.

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4

SECTION 4.0

CONTROL RECORD

4.1 RECORD TYPES

Two types of records comprise an ARCOS report: (1) the *control record* and (2) the *transaction record*. These two types of records have different formats. Section 4 discusses the *control record* while Sections 5 and 6 discuss the *transaction record*.

4.2 CONTROL RECORD

The *control record* ***must*** be the ***very first*** record in each ARCOS report. This record provides the computer system with identifying information about the report being submitted. Both automated and manual reporting use the same *control record* format. The *control record*, illustrated in Exhibit 4.1: Control Record Layout (see page 4-3), contains the following information:

- The *reporting registrant number*.
- An asterisk * to identify this record as a *control record*.
- The *reporting period* covered by this report.
- The registrant's *reporting frequency*.
- The *central reporter's registrant number*, if applicable.

4.3 CONTROL RECORD FORMAT

Positions 1-9: *reporting registrant number*
Position 10: asterisk ***
Positions 11-16: *reporting period **(MMDDYY)***
Position 17: *reporting frequency **(M*** or ***Q)***
Positions 18-26: *central reporter's registrant number* or blank
Positions 27-80: *leave blank*
Special Rules:

1. *reporting period **(MMDDYY)***

   Must be in month, day, and year format (MMDDYY).

   "Day" ***must be*** the last calendar day of the period.

   Monthly: Code "01**31**97" for a January 1997 reporting period

   Quarterly: Code "03**31**97" for a 1997 first quarter reporting period

2. *reporting frequency **(M*** or ***Q)***

   Code "M" for monthly reporting
   Code "Q" for quarterly reporting

3. *central reporter's registrant number*

   Leave this position blank when there is no central reporter or a central reporter is not itself a registered manufacturer or distributor.

4. Positions 27-80 ***must*** be blank.

   The *control record* is ***not*** a *transaction record*. There is ***no*** *transaction identifier* field in the *control record*.

REPORTING REGISTRANT NUMBER	ASTERISK	LAST DAY OF REPORTING PERIOD	REPORTING FREQUENCY	CENTRAL REPORTER'S REGISTRANT NUMBER (IF NEEDED)	
POSITIONS 1-9	POSITION 10	POSITIONS 11-18	POSITION 19	POSITIONS 20-28	POSITIONS 29-80
	*	MMDDYYYY	M or Q	NUMBER or BLANK	BLANK

Exhibit 4.1: Control Record Layout

4.4 ARCOS REPORT

4.4.1 Report's Contents

An ARCOS report consists of a single *control record* and all *transaction records* associated with the ***same*** *reporting registrant number*. Each ARCOS transaction belongs to one of the following five (5) categories: current transactions, corrections, deletions, adjustments, or late transactions. Any ARCOS report may contain all of these transaction types or any combination of them. These transactions ***must*** be grouped together under one corresponding *control record*. The *reporting registrant number*, which appears in both types of records (*control* and *transaction records*), is the link between them.

4.4.2 Placement of Records

All reporters, regardless of whether they are reporting on automated or manual media, ***must include*** the *control record* in each report. The *control record* ***must*** be the ***first*** record in the report. The *transaction records* for the reporting period ***follow*** the *control record*. Error corrections, deletions, adjustments, and late *transaction records* must follow the last current *transaction record* for the reporting period. This arrangement of records within an ARCOS report must be used by all reporting registrants (single reporters, registered and non-registered central reporters). Exhibit 4.2: Record Placement for the ARCOS Report, illustrates the general arrangement of the *control* and *transaction records* within a report.

Arrangement of Control and Transaction Records	
First Record:	*Control Record* for Current Reporting Period.
Next Record(s):	Current Reporting Period *Transaction Records*.
Last Record(s):	Prior Reporting Period *Transaction Records*, if any.

Exhibit 4.2: Record Placement for the ARCOS Report

Example:

An ARCOS registrant's report for the third quarter of 1997 contains transactions for the current reporting period (July, August, and September 1997) as well as corrections, deletions, adjustments, and late *transaction records* for the prior quarters (January through March 1997 and April through June 1997). Exhibit 4.3: ARCOS Registrant's Report, demonstrates the arrangement of these records.

ARCOS Report: Record Arrangement

First Record:	*Control Record* for 1997 Third Quarter.
Next Record(s):	*Transaction Records* for 1997 Third Quarter Transactions.
Last Record(s):	Correction Records for 1997 First and Second Quarter Errors.
	Deletion Records to Remove Records from the Data Base.
	Adjustment Records to Modify Records in the Data Base.
	Insertion Records to Add 1997 First and Second Quarter Late Transactions to the Data Base.

Exhibit 4.3: ARCOS Registrant's Report

4.4.2.1 Record Placement: Automated Single Reporter

The *control record* must be placed ***before the first*** *transaction record* of the current reporting period. See Exhibit 4.2: Record Placement for the ARCOS Report. See Section 4.5.1.1.1 Monthly Reporting or 4.5.1.1.2 Quarterly Reporting for automated single reporter input stream examples.

4.4.2.2 Record Placement: Automated Central Reporter

A *control record* must be placed at the beginning of ***each*** report, ***ahead*** of ***each*** report's first *transaction record* whether all the reports are submitted on one tape, cartridge, or diskette or each report is submitted on a separate tape, cartridge, or diskette. For example, if a central submission contains reports for five ARCOS subsidiary registrants, there will be a total of ***five*** *control records*, ***one*** at the beginning of ***each*** ARCOS registrant's report. For the automated registered central reporter input stream coding examples see Sections 4.5.1.2.1 Monthly Reporting or 4.5.1.2.2

Quarterly Reporting. For the automated non-registered central reporter input stream coding examples see Sections 4.5.1.3.1 Monthly Reporting or 4.5.1.3.2 Quarterly Reporting.

4.4.2.3 Manual Single Reporter

The ***first line*** of the ***first page*** of DEA Form 333 ***must*** be used for the *control record*. Exhibit 4.4: DEA Form 333 Control Record Placement, illustrates the placement of the *control record*.

The preprinted headings on DEA Form 333 identify ***only*** the fields in the *transaction record*. ***Ignore*** these headings when coding the *control record* on the first line of the form. Use the layout given in Exhibit 4.1: Control Record Layout. See Section 4.5.2.1.1 Monthly Reporting or 4.5.2.1.2 Quarterly Reporting for single reporter input stream coding examples.

4.4.2.4 Manual Central Reporter

When central reporters prepare multiple reports, ***each ARCOS registrant's report must begin with a control record.*** The Data Systems Unit (ARCOS) recommends that each report begin on a separate DEA Form 333 with the ***first line*** of the ***first page*** of ***each*** report being used for the *control record*. However, multiple reports can ***follow*** each other on the ***same*** DEA Form 333 coding sheet, as long as the report for each firm ***begins*** with a *control record*. The preprinted headings on DEA Form 333 identify ***only*** the fields in the *transaction record*. ***Ignore*** these headings when coding the *control record* on the first line of the form. Use the layout given in Exhibit 4.1: Control Record Layout.

4.4.2.5 Central Reporter: Record Placement of Prior Transactions

Central reporters with corrections, additions, deletions or insertions for previous reporting periods must place these transactions after the current records for each reporting registrant, but before the control record for the next registrant. Each control record marks the beginning of an ARCOS report for a reporting registrant. A submission from a central reporter can contain several ARCOS reports with data from several different reporting registrants for a reporting period.

ARCOS TRANSACTION REPORTING

DRUG ENFORCEMENT ADMINISTRATION

MAILING INSTRUCTIONS

Retain duplicate for your records.
Mail the Original of completed form to:

Drug Enforcement Administration
ARCOS
P.O. Box 28253
Washington, D.C. 20038 - 8253

INSTRUCTIONS FOR CODING FORM

1. Characters should be printed neatly and conform as closely as possible to examples below.
2. All fields in the transaction (except the transaction code (Field 2) and the delete code (Field 3) are capable of being duplicated without coding the entire field to accomplish this, it is necessary that the first (leftmost) character in each field to be duplicated is coded using an equal (=) sign. The equal sign is the only character which can be used for this purpose.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, Records Management Section, Washington, D.C. 20537, and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0003, Washington, D.C. 20503.

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OMB Approval No. 1117 - 0003

0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z * = ~~K L M~~

REPORTING REGISTRANT NUMBER	TC	NATIONAL DRUG CODE: LABELER CODE / PRODUCT CODE / PKG. CODE	QUANTITY Mkr. of Packages, Volume or Weight	UNIT	ASSOCIATE REGISTRATION NUMBER	DEA ORDER FORM NUMBER	LOT NUMBER (DEA USE ONLY)	STRENGTH	TRANSACTION DATE: MO. / DAY	TRANSACTION IDENTIFIER
PA7777888	*	043097M	USE THE FIRST LINE OF THE FIRST CODING SHEET FOR THE CONTROL RECORD							
=	Y	004194040200	000003		PB0049999				7041500	00001
=	S	054910435860	000008		QA8817923				7042200	00002
=	S	075437514440	000002		AA9900099		00000051		7031900	00063
=	SD	005538196770	000004		AB9900099				7022800	00033
=	PD	S142713281800	000012		CR8712345				7010800	00005
=	PA	S142713281800	000002		CR8772346				7010800	00005
=	SI	318437593440	000205		PB0049931				7022700	00042

DEA Form – 333 (Feb. 1991)

Previous editions may be used.

* Last (Right) Digit of Transaction Year

Exhibit 4.4: DEA Form 333 Control Record Placement

Exhibit 4.5: ARCOS-2 Control Record for Central Reporters and Subsidiaries, illustrates the placement of the *control record* and the relationship between the central reporter and its subsidiaries. If a submission contains reports for five registrants, there will be a total of ***five*** *control record*s. ***One*** *control record* will be placed at the beginning of ***each*** registrant's report (set of coding sheets). See Sections 4.5.2.1.1 Monthly Reporting or 4.5.2.1.2 Quarterly Reporting for registered central reporter input stream coding examples. See Sections 4.5.2.3.1 Monthly Reporting or 4.5.2.3.2 Quarterly Reporting for non-registered central reporter input stream coding examples. Exhibit 4.5 depicts a central reporter with two subsidiaries.

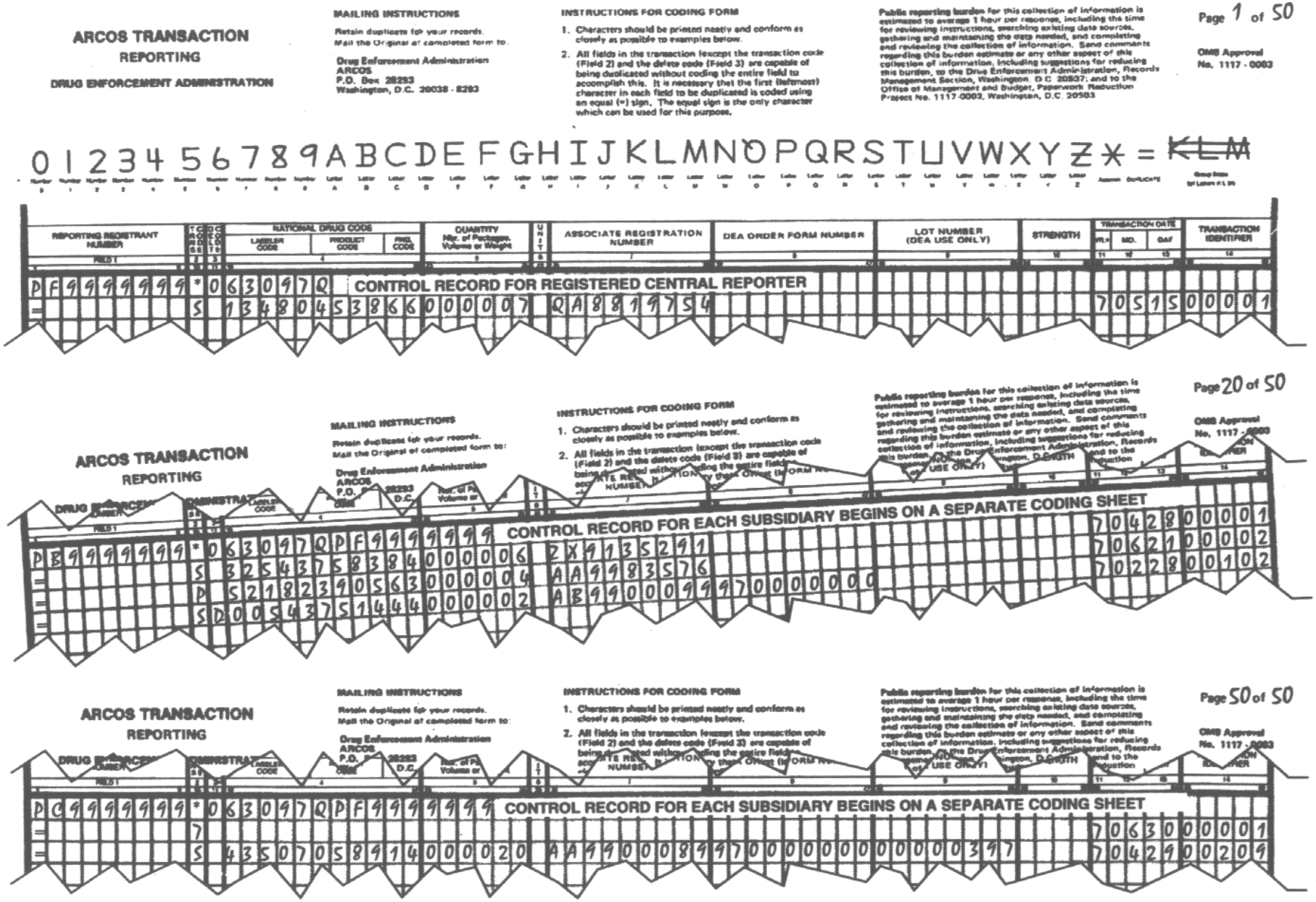

Exhibit 4.5: ARCOS-2 Control Record for Central Reporters and Subsidiaries

4.5 ARCOS INPUT STREAM EXAMPLES

These examples are for instructional purposes only and illustrate the coding of the *control record* and its location in ARCOS report. Examples containing *control records* and associated *transaction records* are provided for both automated (magnetic media) and manual (DEA Form 333) reporting.

Note: In the examples that follow, only the reporting registrant's number and the *transaction identifier* field (a unique, sequential number identifying each transaction) have been used in the *transaction record* illustrations.

4.5.1 Magnetic Media Examples

The reporting of ARCOS transactions on magnetic media is illustrated in Sections 4.5.1.1 through 4.5.1.3. These transactions are reported on either magnetic tape, magnetic cartridge, or magnetic diskette.

4.5.1.1 Automated Single Reporter

One registrant, reporting monthly, reports 681 controlled substance transactions for the *reporting period* ending January 31,1997 while another registrant reporting on a quarterly basis reports 989 transactions for the quarter ending June 30, 1997. The *control record* for a single reporter reporting monthly or a single reporter reporting quarterly is coded as follows:

4.5.1.1.1 Monthly Reporting

Control Record:

Positions 1-9:	PA8888888	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* is arranged as follows:

Control Record:	PA8888888*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PA8888888	...	0000000001
. . .			
. . .			
Last *transaction record*:	PA8888888	...	0000000681

4.5.1.1.2 Quarterly Reporting

Control Record:

Positions 1-9:	PA8888888	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	063097	(last day of *reporting period*)
Positions 17: Q	(quarterly reporting)	
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* is arranged as follows:

Control Record:	PA8888888*063097Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PA8888888	...	0000000001
. . .			
. . .			
Last *transaction record*:	PA8888888	...	0000000989

4.5.1.2 Automated Registered Central Reporter

A monthly registered central reporter submits five (5) ARCOS reports for the reporting period ending January 31, 1997. The first report is for the central reporter itself. The remaining four reports are for other registrants within the registered central reporter's corporate structure.

When a central reporter is reporting for itself, the *control record* positions for the *central reporter's registrant number* (positions 18-26) remain blank. For subsidiaries, the *central reporter's registrant number* is entered in positions 18-26.

4.5.1.2.1 Monthly Reporting

Control Record (Central Reporter, Monthly Reporting):

Positions 1-9:	PF9999999	(*reporting registrant number*) [central reporter's DEA registration number]
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the central reporter is arranged as follows:

Control Record:	PF9999999*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PF9999999	**...**	0000000001
. . .			
. . .			
Last *transaction record*:	PF9999999	**...**	0000000065

Control Record (1st Subsidiary, Monthly Reporting):

Positions 1-9:	PB9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-26:	PF9999999	(*central reporter's registrant number*)
Positions 27-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the first subsidiary is arranged as follows:

Control Record:	PB9999999*013197MPF9999999		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PB9999999	**...**	0000000001
. . .			
. . .			
Last *transaction record*:	PB9999999	**...**	0000000164

Control Record (2nd Subsidiary, Monthly Reporting):

Positions 1-9:	PC9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-26:	PF9999999	(*central reporter's registrant number*)
Positions 27-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the second subsidiary is arranged as follows:

Control Record:	PC9999999*013197MPF9999999		
Transaction Records:	*registrant no*		*transac1ion id*
First *transaction record*:	PC9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PC9999999	...	0000000210

Control Record (3rd Subsidiary, Monthly Reporting):

Positions 1-9:	PD9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-26:	PF9999999	(*central reporter's registrant number*)
Positions 27-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the third subsidiary is arranged as follows:

Control Record:	PD9999999*013197MPF9999999		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PD9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PD9999999	...	0000000300

Control Record (4th Subsidiary, Monthly Reporting):

Positions 1-9:	PE9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-26:	PF9999999	(*central reporter's registrant number)*
Positions 27-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the fourth subsidiary is arranged as follows:

Control Record:	PE9999999*013197MPF9999999		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PE9999999	**...**	0000000001
. . .			
. . .			
Last *transaction record*:	PE9999999	**...**	0000000220

4.5.1.2.2 Quarterly Reporting

A quarterly registered central reporter submits five (5) ARCOS reports for the reporting period ending March 31, 1997. The first report is for the central reporter itself. The remaining four reports are for other registrants within the registered central reporter's corporate structure.

When a central reporter is reporting for itself, the *control record* positions for the *central reporter's registrant number* (positions 18-26) remain blank. For subsidiaries, the *central reporter's registrant number* is entered in positions 18-26.

Control Record (Central Reporter, Quarterly Reporting):

Positions 1-9:	PF9999999	(*reporting registrant number*) [central reporter's DEA registration number]
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the central reporter is arranged as follows:

Control Record:	PF9999999*033197Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PF9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PF9999999	...	0000000065

Control Record (1st Subsidiary, Quarterly Reporting):

Positions 1-9:	PB9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17: Q	(quarterly reporting)	
Positions 18-26:	PF9999999	(*central reporter's registrant number)*
Positions 27-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the first subsidiary is arranged as follows:

Control Record:	PB9999999*033197QPF9999999		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PB9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PB9999999	...	0000000164

Control Record (2nd Subsidiary, Quarterly Reporting):

Positions 1-9:	PC9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17: Q	(quarterly reporting)	
Positions 18-26:	PF9999999	(*central reporter's registrant number)*
Positions 27-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the second subsidiary is arranged as follows:

Control Record:	PC9999999*033197QPF9999999		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PC9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PC9999999	...	0000000210

Control Record (3rd Subsidiary, Quarterly Reporting):

Positions 1-9:	PD9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17:	Q	(quarterly reporting)
Positions 18-26:	PF9999999	(*central reporter's registrant number*)
Positions 27-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the third subsidiary is arranged as follows:

Control Record:	PD9999999*033197QPF9999999		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PD9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PD9999999	...	0000000300

Control Record (4th Subsidiary, Quarterly Reporting):

Positions 1-9:	PE9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18-26:	PF9999999	(*central reporter's registrant number*)
Positions 27-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the fourth subsidiary is arranged as follows:

Control Record:	PE9999999*033197QPF9999999		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PE9999999	**...**	0000000001
. . .			
. . .			
Last *transaction record*:	PE9999999	**...**	0000000220

4.5.1.3 Automated Non-registered Central Reporter

4.5.1.3.1 Monthly Reporting

A non-registered, monthly central reporter submits reports for the reporting period ending January 31, 1997, for five ARCOS registrants within its corporate structure. The following example illustrates this type of submission.

*Control Record (1st Subsidiary, Monthly Reporti*niorting):

Positions 1-9:	PA9999999	(reporting *registrant numb*er)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day o*f reporting peri*od)
Positions 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the first subsidiary is arranged as follows:

Control Record:	PA9999999*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PA9999999	**...**	0000000001
. . .			
. . .			
Last *transaction record*:	PA9999999	**...**	0000000055

Control Record (2nd Subsidiary, Monthly Reporting):

Positions 1-9:	PB9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the second subsidiary is arranged as follows:

Control Record:	PB9999999*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PB9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PB9999999	...	0000000174

Control Record (3rd Subsidiary, Monthly Reporting):

Positions 1-9:	PC9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18 -25:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the third subsidiary is arranged as follows:

Control Record:	PC9999999*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PC9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PC9999999	...	0000000240

Control Record (4th Subsidiary, Monthly Reporting):

Positions 1-9:	PD9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18 -25:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the fourth subsidiary is arranged as follows:

Control Record:	PD9999999*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PD9999999	**...**	0000000001
. . .			
. . .			
Last *transaction record*:	PD9999999	**...**	0000000600

Control Record (5th Subsidiary, Monthly Reporting):

Positions 1-9:	PE9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the fifth subsidiary is arranged as follows:

Control Record:	PE9999999*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*	PE9999999	**...**	0000000001
. . .			
. . .			
Last *transaction record*	PE9999999	**...**	0000000280

4.5.1.3.2 Quarterly Reporting

A non-registered central reporter submits reports for the quarterly reporting period ending March 31, 1997, for five ARCOS registrants within its corporate structure.

Control Record (1st Subsidiary, Quarterly Reporting):

Positions 1-9:	PA9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the first subsidiary is arranged as follows:

Control Record:	PA9999999*033197Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PA9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PA9999999	...	0000000055

Control Record (2nd Subsidiary, Quarterly Reporting):

Positions 1-9:	PB9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18 -25:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the second subsidiary is arranged as follows:

Control Record:	PB9999999*033197Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PB9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PB9999999	...	0000000174

Control Record (3rd Subsidiary, Quarterly Reporting):

Positions 1-9:	PC9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the third subsidiary is arranged as follows:

Control Record:	PC9999999*033197Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PC9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PC9999999	...	0000000240

Control Record (4th Subsidiary, Quarterly Reporting):

Positions 1-9:	PD9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17: Q		quarterly reporting)
Positions 18-80:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the fourth subsidiary is arranged as follows:

Control Record:	PD9999999*033197Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PD9999999	...	0000000001
. . .			
. . .			
Last *transaction record*:	PD9999999	...	0000000600

Control Record (5th Subsidiary, Quarterly Reporting):

Positions 1-9:	PE9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	033197	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18 -25:	*leave blank*	

The magnetic media input stream containing both the *control record* and *transaction records* for the fifth subsidiary is arranged as follows:

Control Record:	PE9999999*033197Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*	PE9999999	...	0000000001
. . .			
. . .			
Last *transaction record*	PE9999999	...	0000000280

4.5.2 Manual Media Examples

The reporting of ARCOS transactions on manual media is illustrated in Sections 4.5.2.1 through 4.5.2.4. These transactions are reported on DEA Form 333 coding sheets.

4.5.2.1 Manual Single Reporter

The *control record* for monthly and quarterly reporting is coded as follows:

4.5.2.1.1 Monthly Reporting

A registrant reporting monthly reports 251 controlled substance transactions for the reporting period ending January 31, 1997.

Control Record

Positions 1-9:	PA7777888	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* is arranged as follows:

Control Record:	PA7777888*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PA7777888	**...**	00001
. . .			
. . .			
Last *transaction record*:	PA7777888	**...**	00251

4.5.2.1.2 Quarterly Reporting

A registrant reporting quarterly reports 551 controlled substance transactions for the reporting period ending September 30, 1997.

Control Record

Positions 1-9:	PA7777888	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	093097	(last day of *reporting period*)
Positions 17: Q	(quarterly reporting)	
Positions 18-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* is arranged as follows:

Control Record:	PA7777888*093097Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PA7777888	**...**	00001
. . .			
. . .			
Last *transaction record*:	PA7777888	**...**	00551

4.5.2.2 Manual Registered Central Reporter

As was previously stated (Section 4.4.2.4, Manual Central Reporter), ***each registrant's report must*** begin with a central record.

4.5.2.2.1 Monthly Reporting

A monthly registered central reporter submits three (3) ARCOS reports for the reporting period ending January 31, 1997. The first report is for the central reporter itself. The remaining two reports are for other registrants within the registered central reporter's corporate structure.

Control Record (Central Reporter, Monthly Reporting):

Positions 1-9:	PF9996666	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* is arranged as follows:

Control Record:	PF9996666*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PF9996666	**...**	00001
. . .			
. . .			
Last *transaction record*:	PF9996666	**...**	00065

Control Record (1st Subsidiary, Monthly Reporting):

Positions 1-9:	PB9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of reporting period)
Positions 17: M		(monthly reporting)
Positions 18-80:	PF9996666	(*central reporter's registrant number*)

The coded DEA Form 333 containing both the *control record* and *transaction records* for the first subsidiary is arranged as follows:

Control Record:	PB9999999*013197MPF9996666		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PB9999999	...	00001
. . .			
. . .			
Last *transaction record*:	PB9999999	...	00164

Control Record (2nd Subsidiary, Monthly Reporting):

Positions 1-9:	PC9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-80:	PF9996666	(*central reporter's registrant number*)

The coded DEA Form 333 containing both the *control record* and *transaction records* for the second subsidiary is arranged as follows:

Control Record:	PC9999999*013197MPF9996666		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PC9999999	...	00001
. . .			
. . .			
Last *transaction record*:	PC9999999	...	00210

4.5.2.2.2 Quarterly Reporting

A quarterly registered central reporter submits three (3) ARCOS reports for the reporting period ending December 31, 1997. The first report is for the central reporter itself. The remaining two reports are for other registrants within the registered central reporter's corporate structure.

Control Record (Central Reporter, Quarterly Reporting):

Positions 1-9:	PF9996666	(*reporting registrant number*) [central reporter's DEA registration number]
Position 10:	*	(asterisk)
Positions 11-16:	123197	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* for the central reporter is arranged as follows:

Control Record:	PF9996666*123197Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PF9996666	...	00001
. . .			
. . .			
Last *transaction record*:	PF9996666	...	00065

Control Record (1st Subsidiary, Quarterly Reporting):

Positions 1-9:	PB9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	123197	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18-26:	PF9996666	(*central reporter's registrant number)*
Positions 27-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* for the first subsidiary is arranged as follows:

Control Record:	PB9999999*123197QPF9996666		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PB9999999	...	00001
. . .			
. . .			
Last *transaction record*:	PB9999999	...	00164

Control Record (2nd Subsidiary, Quarterly Reporting):

Positions 1-9:	PC9999999	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	123197	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18-26:	PF9996666	(*central reporter's registrant number*)
Positions 27-80:	leave blank	

The coded DEA Form 333 containing both the *control record* and *transaction records* for the second subsidiary is arranged as follows:

Control Record:	PC9999999*123197QPF9996666		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PC9999999	**...**	00001
. . .			
. . .			
Last *transaction record*:	PC9999999	**...**	00210

4.5.2.3 Manual Non-registered Central Reporter

As was previously stated (Section 4.4.2.4 Manual Central Reporters), ***each registrant's report begins with a control record.*** For a non-registered central reporter, the *central reporter's registrant number* (positions 18-26) remains blank.

4.5.2.3.1 Monthly Reporting

A monthly, non-registered central reporter submits reports for the reporting period ending January 31, 1997, for three ARCOS registrants within its corporate structure.

Control Record (1st Subsidiary, Monthly Reporting):

Positions 1-9:	PA5555555	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Positions 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* for the first subsidiary is arranged as follows:

Control Record:	PA5555555*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PA5555555	**...**	00001
. . .			
. . .			
Last *transaction record*:	PA5555555	**...**	00055

Control Record (2nd Subsidiary, Monthly Reporting):

Positions 1-9:	PB1234567	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of *reporting period*)
Position 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* for the second subsidiary is arranged as follows:

Control Record:	PB1234567*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*	PB1234567	**...**	00001
. . .			
. . .			
Last *transaction record*	PB1234567	**...**	00174

Control Record (3rd Subsidiary, Monthly Reporting):

Positions 1-9:	PC9876543	registrant's registrant number)
Position 10:	*	(asterisk)
Positions 11-16:	013197	(last day of reporting period)
Positions 17: M		(monthly reporting)
Positions 18-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* for the third subsidiary is arranged as follows:

Control Record:	PC9876543*013197M		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*	PC9876543	**...**	00001
. . .			
. . .			
Last *transaction record*	PC9876543	**...**	00240

4.5.2.3.2 Quarterly Reporting

A quarterly, non-registered central reporter submits three (3) ARCOS reports for subsidiaries within its corporate structure for the quarterly reporting period ending September 30, 1997.

Control Record (1st Subsidiary, Quarterly Reporting):

Positions 1-9:	PA5555555	(*reporting registrant number*)
Position 10: *		(asterisk)
Positions 11-16:	093097	(last day of *reporting period*)
Positions 17: Q		(quarterly reporting)
Positions 18-80:	*leave blank*	

The coded DEA 333 containing both the *control record* and *transaction records* for the first subsidiary is arranged as follows:

Control Record:	PA5555555*093097Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*:	PA5555555	**...**	00001
. . .			
. . .			
Last *transaction record*:	PA5555555	**...**	00055

Control Record (2nd Subsidiary, Quarterly Reporting):

Positions 1-9:	PB1234567	(*reporting registrant number*)
Position 10:	*	(asterisk)
Positions 11-16:	093097	(last day of *reporting period*)
Position 17:	Q	(quarterly reporting)
Positions 18-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* for the second subsidiary is arranged as follows:

Control Record:	PB1234567*093097Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*	PB1234567	...	00001
. . .			
. . .			
Last *transaction record*	PB1234567	...	00174

Control Record (3rd Subsidiary, Quarterly Reporting):

Positions 1-9:	PC9876543	(*reporting registrant number*)
Position 10: *		(asterisk)
Positions 11-16:	093097	(last day of reporting period)
Positions 17: Q		(quarterly reporting)
Positions 18-80:	*leave blank*	

The coded DEA Form 333 containing both the *control record* and *transaction records* for the third subsidiary is arranged as follows:

Control Record:	PC9876543*093097Q		
Transaction Records:	*registrant no*		*transaction id*
First *transaction record*	PC9876543	...	00001
. . .			
. . .			
last *transaction record*	PC9876543	...	00240

5

SECTION 5.0

TRANSACTION RECORD

5.1 TRANSACTION RECORD

Controlled substance transactions are reported using the ARCOS *transaction record*. This section discusses the *transaction record* fields that apply to all manufacturers and distributors of reportable controlled substances. Section 6 discusses *transaction record* fields that apply ***only*** to manufacturers.

The ARCOS *transaction record* has two formats: one format for reporting controlled substance transactions on magnetic tape, cartridge, or diskette (automated reporting) and another, slightly different format, for reporting transactions on DEA Form 333 (manual reporting). Exhibit 5.1: Transaction Record Formats, illustrates the record layouts for both formats. The differences between the two formats are:

a. The automated reporting format contains an additional field, the *document Identifier* field, which identifies the transaction as having been generated by an automated system.

b. The *transaction date* field is a ***six-digit*** field in the automated reporting format and a ***five-digit*** field in the manual reporting format.

c. The *quantity* field is an ***eight-position*** field in the automated reporting format and a ***six-position*** field in the manual reporting format

FIELD NAME	AUTOMATED			MANUAL (DEA Form 333)		
	FIELD NUMBER	FIELD LENGTH	POSITION LOCATION	FIELD NUMBER	FIELD LENGTH	COLUMN LOCATION
REPORTING REGISTRANT NUMBER	1	9	1-9	1	9	1-9
TRANSACTION CODE	2	1	10	2	1	10
ACTION INDICATOR (FORMERLY DELETE INDICATOR)	3	1	11	3	1	11
NATIONAL DRUG CODE (NDC NUMBER)	4	11	12-22	4	11	12-22
QUANTITY	5	8	23-30	5	6	23-28
UNIT	6	1	31	6	1	29
ASSOCIATE REGISTRANT NUMBER	7	9	32-40	7	9	30-38
DEA ORDER FORM NUMBER	8	9	41-49	8	9	39-47
TRANSACTION DATE	9	6	50-55	11-13	5	60-64
CORRECTION NUMBER (FORMERLY LOT NUMBER)	10	8	56-63	9	8	48-55
STRENGTH	11	4	64-67	10	4	56-59
TRANSACTION IDENTIFIER	12	10	68-77	14	5	65-69
DOCUMENT IDENTIFIER	13	3	78-80	NONE	NONE	NONE

Exhibit 5.1: Transaction Record Formats

5.2 DEA FORM 333: DUPLICATING DATA

ARCOS uses the equal sign, "=", to indicate that the data recorded in a *transaction record* field on DEA Form 333 is to be duplicated in subsequent *transaction records*. Under ARCOS the "=" is called the "duplicate sign." The duplicate sign (=) may be used to avoid repeatedly writing identical data within a field. The duplicate sign (=) ***must*** be coded in the first position of each field being duplicated. Examples applying to sections 5.2 and 5.2.1 illustrating the use of the duplicate sign are found in:

a. Exhibit 5.2: Using the Duplicate Sign, Single Reporter and

b. Exhibit 5.3: Using the Duplicate Sign, Central Reporter

5.2.1 DEA Form 333: Duplicating Transaction Date

The *transaction date* field is composed of three segments: Fields 11, 12, and 13 (year, month, and day). These three segments ***must*** be considered one, single field for duplicating purposes. Therefore, the entire *transaction date* ***must be the same*** when using the duplicate sign.

ARCOS TRANSACTION REPORTING

DRUG ENFORCEMENT ADMINISTRATION

MAILING INSTRUCTIONS

Retain duplicate for your records
Mail the Original of completed form to:

Drug Enforcement Administration
ARCOS
P.O. Box 28293
Washington, D.C. 20038 - 8293

INSTRUCTIONS FOR CODING FORM

1. Characters should be printed neatly and conform as closely as possible to examples below.
2. All fields in the transaction (except the transaction code (Field 2) and the delete code (Field 3) are capable of being duplicated without coding the entire field by accomplish this. It is necessary that the first (leftmost) character in each field to be duplicated is coded using an equal (=) sign. The equal sign is the only character which can be used for this purpose.

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, Records Management Section, Washington, D.C. 20537, and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0003, Washington, D.C. 20503

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OMB Approval No. 1117 - 0003

0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z * = ~~K L M~~

Number 0 · Number 1 · Number 2 · Number 3 · Number 4 · Number 5 · Number 6 · Number 7 · Number 8 · Number 9 · Letter A · Letter B · Letter C · Letter D · Letter E · Letter F · Letter G · Letter H · Letter I · Letter J · Letter K · Letter L · Letter M · Letter N · Letter O · Letter P · Letter Q · Letter R · Letter S · Letter T · Letter U · Letter V · Letter W · Letter X · Letter Y · Letter Z · Asterisk · DUPLICATE · Gross Gross of Letters K L Ms

REPORTING REGISTRANT NUMBER (FIELD 1)	TRANSACTION CODE (FIELD 2)	DELETE CODE (FIELD 3)	NATIONAL DRUG CODE (FIELD 4): LABELER CODE	PRODUCT CODE	PKG. CODE	QUANTITY Nbr. of Packages, Volume or Weight (FIELD 5)	UNIT (FIELD 6)	ASSOCIATE REGISTRATION NUMBER (FIELD 7)	DEA ORDER FORM NUMBER (FIELD 9)	LOT NUMBER (DEA USE ONLY) (FIELD 8)	STRENGTH (FIELD 10)	TRANSACTION DATE (FIELD 11): YR.*	MO.	DAY	TRANSACTION IDENTIFIER (FIELD 12)
PA7777888	*	0	43097	M											
=	S		00419	40402	00	000003		PB0999999	970000000		05007	04	15	000001
=	=		=	=	=	=	=	=	=	=	=	=	=	=	000002
=	=		13480	45386	60	000002		QA8819754	960000000		=	04	20	000003
=	=		=	=	=	=	=	=	=	=	=	=	=	=	000004
=	=		=	=	=	=	=	=	=	=	0900	=	=	=	000005
=	=		=	=	=	=	=	=	=	=	=	=	=	=	000006
=	=		=	=	=	=	=	=	=	=	=	=	=	=	000007
=	=		43507	05891	40	000001		AA9900089	950000000		=	04	30	000008

DATE MUST BE THE SAME

DEA Form — 333 (Feb 1991)

Previous editions may be used.

* Last Digit of Transaction Year

Exhibit 5.2: Using the Duplicate Sign, Single Reporter

ARCOS TRANSACTION REPORTING

DRUG ENFORCEMENT ADMINISTRATION

MAILING INSTRUCTIONS

Retain duplicate for your records.
Mail the Original of completed form to:

Drug Enforcement Administration
ARCOS
P.O. Box 28283
Washington, D.C. 20038 - 8283

INSTRUCTIONS FOR CODING FORM

1. Characters should be printed neatly and conform as closely as possible to examples below.
2. All fields in the transaction (except the transaction code (Field 2) and the delete code (Field 3) are capable of being duplicated without coding the entire field to accomplish this. It is necessary that the first (leftmost) character in each field to be duplicated is coded using an equal (=) sign. The equal sign is the only character which can be used for this purpose.

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0 1 2 3 4 5 6 7 8 9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z * = ~~K L M~~

Number Number Number Number Number Number Number Number Number Number Letter Asterisk DUPLICATE

Group Entries for Letters K L M

REPORTING REGISTRANT NUMBER	TC	DC	NATIONAL DRUG CODE: LABELER CODE	NATIONAL DRUG CODE: PRODUCT CODE	NATIONAL DRUG CODE: PKG. CODE	QUANTITY (Nbr. of Packages, Volume or Weight)	UNIT	ASSOCIATE REGISTRATION NUMBER	DEA ORDER FORM NUMBER	LOT NUMBER (DEA USE ONLY)	STRENGTH	TRANSACTION DATE: YR.*	TRANSACTION DATE: MO.	TRANSACTION DATE: DAY	TRANSACTION IDENTIFIER
FIELD 1	1	2	4			5	6	7	8	9	10	11	12	13	14
PF999999999	*	D	430917M												
=	S		1348045386			000002		QA8819754	960000000			7	04	30	0001
=	=		=			=		=	=			=	=	=	0002
PB999999999	*	D	430917MPF	99999	9999										
=	P		435070589	1140		000010		RT8888888	896000000		0400	7	04	01	0003
=	S		=			=		=	=		=	=	=	=	0004
=	S		=			000030		=	=			7	04	02	0005
=	=		521823905	63		=		AA9983576	950000000		0500	=	=	=	0006
=	=		=			=		=	=		=	=	=	=	0007
PC999999999	*	D	430917MPF	99999	9999										
=	P		005538196	77		000009		CR8712345	=		=	7	04	28	0008
=	=		=			=		=	=		=	=	=	=	0009
=	=		=			=		=	=		=	=	=	=	0010
=	=		=			=		=	=		=	=	=	=	0011
=	=		=			=		=	=		=	=	=	=	0012
=	=		=			=		=	=		=	=	=	=	0013
=	=		=			=		=	=		=	=	=	=	0014

DATE MUST BE THE SAME

* Last (Right) Digit of Transaction Year

DEA Form — 333 (Feb. 1991)

Previous editions may be used.

Exhibit 5.3: Using the Duplicate Sign, Central Reporter

5.3 REPORTING REGISTRANT NUMBER

5.3.1 Definition: Reporting Registrant Number

The *reporting registrant number* is the DEA registration number identifying the location where the controlled substance activities being reported have occurred. This is a 9-character field.

5.3.2 Specifications: Reporting Registrant Number

a. Field Number: 1
b. Field Name: *reporting registrant number*
c. Field Length: 9 Characters
d. Positions/Columns: 1-9
e. Type: Alphanumeric
f. Special Rules:
    1. Mandatory Entry
    2. Use Capital Letters for Alphabetic Data
    3. Position/Column 1 is always 'P' or 'R'

5.3.3 Discussion: Reporting Registrant Number

A central reporter uses its own registrant reporting number when reporting for itself and the subsidiaries's registrant reporting number when reporting for a subsidiary.

5.4 TRANSACTION CODE

5.4.1 Definition: Transaction Code

The *transaction code* is a single-character field which identifies each specific ARCOS-reportable activity.

5.4.2 Specifications: Transaction Code

a. Field Number: 2
b. Field Name: *transaction code*
c. Field Length: 1 Character
d. Position/Column: 10
e. Type: Alphanumeric

f. Special Rules:
    1. Only Specific Codes Permitted
    2. Mandatory Entry
    3. Use Capital Letters for Alphabetic Data

5.4.3 Discussion: Transaction Code

Manufacturers and distributors are responsible for reporting all ARCOS activities and inventories. The *transaction code* field identifies the reporting registrant's controlled substance acquisitions, dispositions, inventories, and miscellaneous transactions. The transaction codes listed below have been grouped into four categories for ease in selecting the correct code under which to report a specific business or manufacturing activity. These four categories are: inventory, acquisition, disposition, and miscellaneous. They are discussed in detail in Section 5.5 through 5.7. See Appendix 1, ARCOS Transaction Matrix: Automated Reports or Appendix 2, ARCOS Transaction Matrix: Manual Reports, to determine which fields must be completed for a specific *transaction code*.

Inventory Transaction Codes

transaction code 1: Schedule Change Inventory
transaction code 3: Year-End Inventory
transaction code 4: Year-End In-Process Inventory (manufacturers only)
transaction code 5: Special Inventory
transaction code 8: No Year-End Inventory

Acquisition Transaction Codes (Increases to Inventory)

transaction code P: Purchase or Receipt
transaction code R: Return
transaction code V: Unsolicited Return
transaction code G: Government Supplied
transaction code W: Recovered Waste (manufacturers only)
transaction code M: Manufactured (manufacturers only)
transaction code L: Reversing (manufacturers only)
transaction code J: Return of Sample to Inventory (manufacturers only)

Disposition Transaction Codes (Decreases to Inventory)

transaction code S: Sale, Disposition, or Transfer
transaction code Y: Destroyed
transaction code T: Theft
transaction code Z: Receipt by Government (seizures, samples, etc.)
transaction code N: Nonrecoverable Waste (manufacturers only)
transaction code U: Used in Production (manufacturers only)
transaction code Q: Sampling (manufacturers only)
transaction code K: Used in Preparations (manufacturers only)

Miscellaneous Transaction Codes

transaction code 7: No ARCOS Activity for the Current Reporting Period
transaction code F: Reorder DEA Form 333
transaction code X: Lost-in-Transit

5.5 INVENTORY TRANSACTION CODES

Transaction code 1, Schedule Change Inventory; *transaction code 3*, Year-End Physical Inventory; *transaction code 4*, In-Process Inventory; and *transaction code 5*, Special Inventory are used when reporting inventory data to DEA (ARCOS).

5.5.1 Code 1: Schedule Change Inventory

Transaction code 1, Schedule Change Inventory, is used when reporting bulk or dosage form products that become reportable controlled substances due to a controlled substance schedule change. Specific instructions will be provided by DEA (ARCOS) when a controlled substance schedule change affecting ARCOS reporting occurs.

Example:

Prior to March 21, 1991, glutethimide was a Schedule III controlled substance which was only reportable by ARCOS registrants actually manufacturing the drug. On March 21, 1991, glutethimide became a Schedule II controlled substance. At this point, glutethimide became reportable by all ARCOS registrants. All ARCOS registrants not previously reporting this controlled substance were required to report a Schedule Change Inventory Transaction (*transaction code 1*), if glutethimide was in their inventory on March 21, 1991.

Acquisition After Report

ARCOS registrants acquiring new stock after a Schedule Change Inventory report has been submitted, report this new stock as a "purchase" (*transaction code P*) or as another type of acquisition transaction when reporting that period's activities.

Out-of-Stock *or* Do Not Carry

ARCOS registrants that carry a newly-reportable controlled substance, but are out-of-stock ***or*** ARCOS registrants that do not carry a newly-reportable controlled substance ***must not*** report a Schedule Change Inventory. If an ARCOS registrant acquires the newly-reportable controlled substance at a later date, this acquisition would be reported as a "purchase" (*transaction code P*) or as another type of acquisition transaction when reporting that period's activities.

Exhibit 5.4: Schedule Change Reporting Requirements, summarizes reporting requirements when a controlled substance schedule change makes a formerly non-reportable controlled substance reportable.

Inventory Status	ARCOS Transaction Code	Submission Required
Out-of-stock	None	Schedule Change Inventory Not Required
In-stock	*transaction code 1*	Schedule Change Inventory Required
Received After Schedule Change Date	*transaction code P* or Other Applicable Acquisition Code	Schedule Change Inventory Not Required

Exhibit 5.4: Schedule Change Reporting Requirements

5.5.2 Code 3: Year-End Physical Inventory

All ARCOS registrants are required to take a ***physical,*** year-end inventory (YEI). This inventory ***must*** reflect the ***actual amount*** of ***each*** reportable controlled substance on the registrant's premises as of the close of business on December 31st of ***each*** year. This is the ***only valid date*** which is accepted for *transaction code* 3. If the year-end inventory report is ***not*** dated December 31, the *transaction record* is ***rejected***. If year-end inventory transactions are included in the December or fourth quarter report, the reporting registrant ***must*** write **"YEI INCLUDED"** in the **"*Notes*"** block of the bar code label. This indicates that the December or fourth quarter report also contains the year-

end inventory report and will ***prevent*** the registrant from being placed in a delinquent reporting status.

5.5.3 Code 4: Year-end In-process Inventory

On December 31st of each year, a manufacturer may have some quantities of controlled substances that are still in the manufacturing production chain (i.e., not in a bulk or finished dosage form). The amount of controlled substance at this stage of the production chain is termed an "In-process Inventory" *quantity*. Year-end In-process Inventory is reported using *transaction code 4*. The Year-end In-process Inventory is to be taken at the close of business on December 31st of the reporting year. This is the ***only date*** which will be accepted for transaction code 4. See Section 6, Manufacturing Activities, for examples of In-process Inventory reporting.

5.5.4 Code 5: Special Inventory

A Special Inventory is any inventory other than a Year-end, Year-end In-process, or Schedule Change Inventory being taken at the ***direction*** of DEA. Report a Special Inventory using transaction code 5.

5.5.5 Code 8: No Year-End Inventory

Transaction code 8 is used to report zero (0) year-end inventory. If, at the close of business on December 31st, an ARCOS registrant has no (i.e., zero) ***physical*** inventory for ***all*** the reportable controlled substances that it handles, the firm ***must*** report this ***lack*** of physical inventory to DEA (ARCOS). It is ***not*** necessary to report the lack of inventory for each reportable controlled substance that the firm has handled through the year. A single transaction code 8 is sufficient. The "no-year-end inventory" report will ***prevent*** DEA (ARCOS) from placing the registrant in a delinquent reporting status. *transaction code 8* requires the following fields:

- *reporting registrant number*
- *transaction code 8*
- *transaction date* (December 31st of each year)
- *transaction Identifier*

5.6 ACQUISITION TRANSACTION CODES

An ARCOS registrant can acquire controlled substances by buying them, by having previously sold controlled substances returned, or by receiving them from the government. If the ARCOS registrant is a manufacturer, the registrant can acquire controlled substances by four additional means: (1) manufacturing them, (2) recovering them from manufacturing waste, (3) having samples of controlled substances returned, or (4) by decomposing a substance into its component substances; one of which is a controlled

substance. Acquisitions of controlled substances, irrespective of the manner in which they are acquired, increase the ARCOS registrant's inventory.

5.6.1 Code P: Purchase or Other Receipt

Transaction code P, purchase or other receipt, is used to report controlled substance acquisitions under three different scenarios:

a. The acquisition of a controlled substance by one ARCOS registrant from another.

b. The transfer of a controlled substance from one physical location to another.

c. Establishing the initial stock on hand of a controlled substance for a new ARCOS registrant.

Controlled substances that are ***shipped directly*** from a supplier to an ARCOS registrant's customer (third party shipments) and are ***never physically on the registrant's premises***, (i.e., a drop shipment) are reported to DEA (ARCOS) by the supplier and the recipient. The ARCOS registrant ***must not*** report these transactions.

5.6.2 Code R: Return

Transaction code R is used to report the receipt of returned controlled substances when the manufacturer or distributor ***requests*** their return. Returns reported under *transaction code R* do ***not*** necessarily involve a monetary transaction. Reportable controlled substances received by a supplier may include substances being returned for credit, salvage, re-work, or non-GMP (good manufacturing process) quality, as well as outdated or unused controlled substances.

5.6.3 Code V: Unsolicited Return

Transaction code V is used to report the receipt of an unsolicited return of a reportable controlled substance. An "unsolicited return" is a return that has ***not*** been ***requested*** by the manufacturer or distributor. The situations needing *transaction code V* are described below and summarized in Exhibit 5.5: Using Transaction Code V.

UNSOLICITED RETURN					
	SHIPPER'S IDENTITY	SCHEDULE	ORDER FORM NUMBER REQUIRED?	TRANSACTION CODE	ASSOCIATE REGISTRANT NUMBER ENTRY
1	Unknown	III narcotic	NO	V	"UNKNOWN"
2	Unknown	I, II	YES	V	"UNKNOWN"
3	Known	III narcotic	NO	V	USE SHIPPER'S DEA REGISTRATION NUMBER
4	Known	I, II	YES	V	USE SHIPPER'S DEA REGISTRATION NUMBER

Exhibit 5.5: Using Transaction Code V

Unknown Shipper

a. Use *transaction code V* when a Schedule III narcotic shipment is received ***without*** any identifying markings indicating the name of the firm that shipped the drugs. In the *associate registrant number* field (Field 7), enter "**UNKNOWN**" in all ***capital letters*** and ***left justified***.

b. Use *transaction code* V when a Schedule I or II product is received ***without*** the prior issuance of an order form (U.S. Official Order Forms - Schedules I & II) DEA Form 222, ***and without any*** identifying markings indicating the name of the firm that shipped the product. In the *associate registrant number* field (Field 7), enter "**UNKNOWN**" in all ***capital letters*** and ***left justified***. Additionally, a DEA Order Form Number ***must*** be acquired to cover the shipment. An "after-the-fact" DEA Order Form Number ***must*** be issued by the receiving firm using its ***own blank*** Order Form, ***after*** obtaining approval from the local DEA field office.

Known Shipper

c. Use *transaction code V* when a Schedule III narcotic shipment is received ***without*** prior notification and the shipper is ***known***. If the registrant decides to keep the shipment, the registrant must obtain the approval of the local DEA field office. The ***shipper's*** DEA Registration Number is entered into the *associate registrant number* field (Field 7).

d. Use *transaction code V* when a Schedule I or II shipment is received ***without*** the prior issuance of an order form, DEA Form 222, and the shipper is ***known***. When such a shipment is received, the recipient firm ***must***: (1) obtain the approval of the local DEA field office to issue an "after-the-fact" DEA order form number and (2) issue the DEA order form number using its ***own blank*** order form. The ***shipper's*** DEA registration number is entered into the *associate registrant number* field (Field 7) and the order form number is entered in the *DEA order form number* field (Field 8).

5.6.4 Code G: Government Supplied

Transaction code G is used when the government supplies controlled substances or returns seized materials or samples to the reporting registrant. The registration number of the DEA or FDA divisional office is required in the *associate registrant number* field (Field 7). Contact your local DEA office to obtain the appropriate associate registrant number, if it is ***unknown***.

5.6.5 Manufacturing Acquisition Codes

The following acquisition transaction codes are discussed in Section 6, Manufacturing Activities:

transaction code W	Recovered Waste (Manufacturers Only)
transaction code M	Manufactured (Manufacturers Only)
transaction code L	Reversing (Manufacturers Only)
transaction code	Return of Sample to Inventory (Manufacturers Only)

5.7 DISPOSITION TRANSACTION CODES

Controlled substances can be sold, destroyed, taken by the government, or stolen (theft). Under the manufacturing process there are a number of additional ways to dispose of controlled substances: (1) non-recoverable waste, (2) used in manufacturing, (3) distribution of samples, and (4) used in preparations. Dispositions of controlled substances, irrespective of the manner in which they are disposed, decrease the ARCOS registrant's inventory.

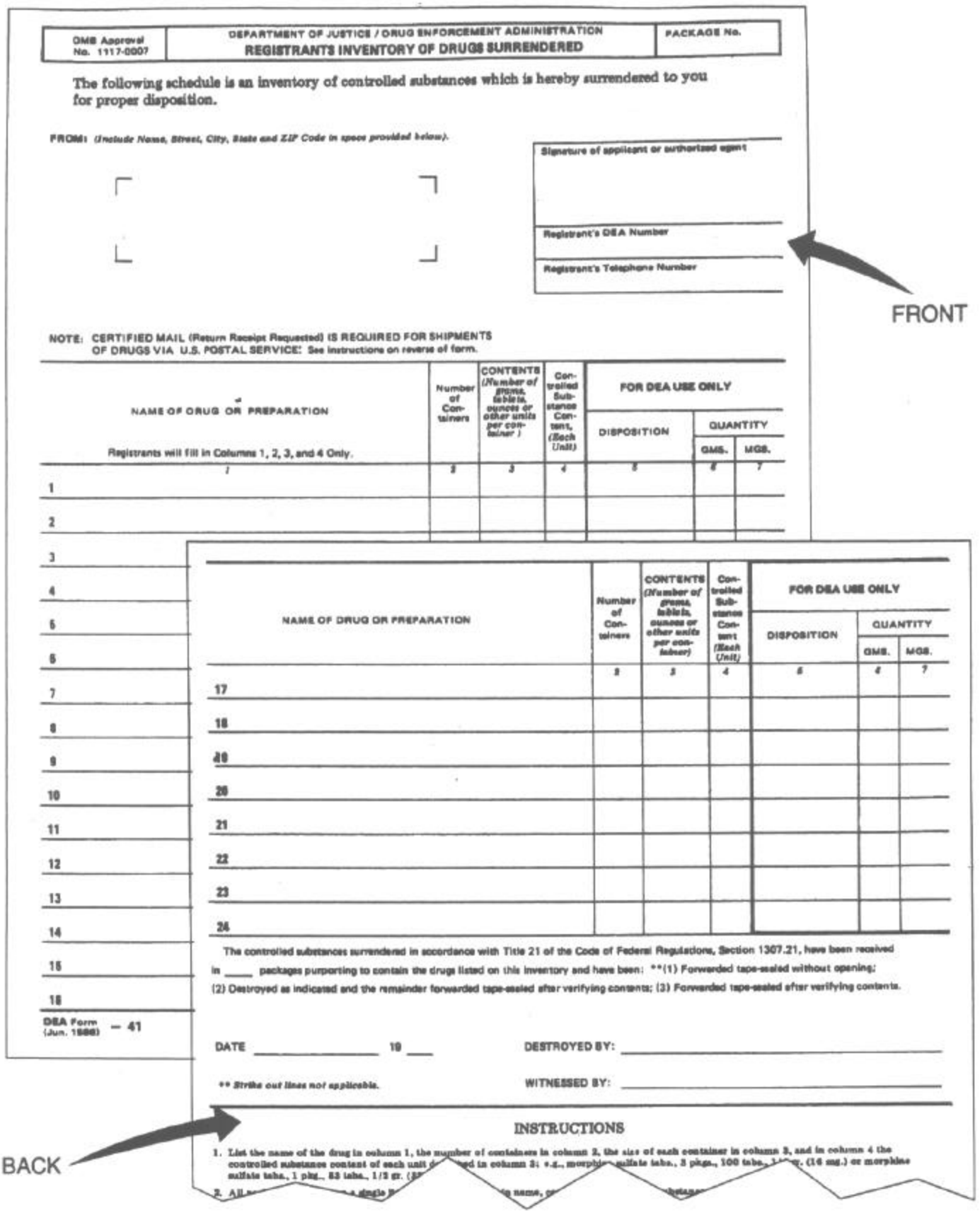
5.7.1 Code S: Sale, Disposition, or Transfer

Transaction code S is used when a controlled substance is physically transferred to another DEA registrant. This is ***not*** necessarily a monetary transaction. Samples to customers are included in this category. However, a sample that does ***not*** leave the ARCOS registrant's premises is reported as a *transaction code Q*. See Section 6, Manufacturing Codes. The sale of reportable controlled substances reduces the manufacturer's or distributor's inventory.

In cases where a controlled substance is shipped directly from a supplier to an ARCOS registrant's customer and is ***never physically*** on the registrant's premises (e.g., the registrant only does the billing), the registrant ***must not*** report the transaction. The supplier and the recipient do the reporting.

5.7.2 Code Y: Destroyed

Transaction code Y is used for reporting authorized destructions of controlled substances. Enter the registration number of the local DEA area office in the *associate registrant number* field (Field 7). If necessary, contact the DEA area office or the Data Systems Unit (ARCOS) to obtain the DEA registration number. For all destructions,
DEA Form 41, Registrants Inventory of Drugs Surrendered, ***must*** be filed with the local DEA area office. Exhibit 5.6: DEA Form 41, contains a sample form.



OMB Approval No. 1117-0007

DEPARTMENT OF JUSTICE / DRUG ENFORCEMENT ADMINISTRATION

REGISTRANTS INVENTORY OF DRUGS SURRENDERED

PACKAGE No.

The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: *(Include Name, Street, City, State and ZIP Code in space provided below).*

Signature of applicant or authorized agent

Registrant's DEA Number

Registrant's Telephone Number

FRONT

NOTE: CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse of form.

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1, 2, 3, and 4 Only.	Number of Containers	CONTENTS *(Number of grams, tablets, ounces or other units per container)*	Controlled Substance Content, *(Each Unit)*	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS.	MGS.
1	2	3	4	5	6	7
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						

The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in ____ packages purporting to contain the drugs listed on this inventory and have been: **(1) Forwarded tape-sealed without opening; (2) Destroyed as indicated and the remainder forwarded tape-sealed after verifying contents; (3) Forwarded tape-sealed after verifying contents.

DEA Form (Jun. 1988) — 41

DATE _____ 19 ___

DESTROYED BY: _____

** *Strike out lines not applicable.*

WITNESSED BY: _____

BACK

INSTRUCTIONS

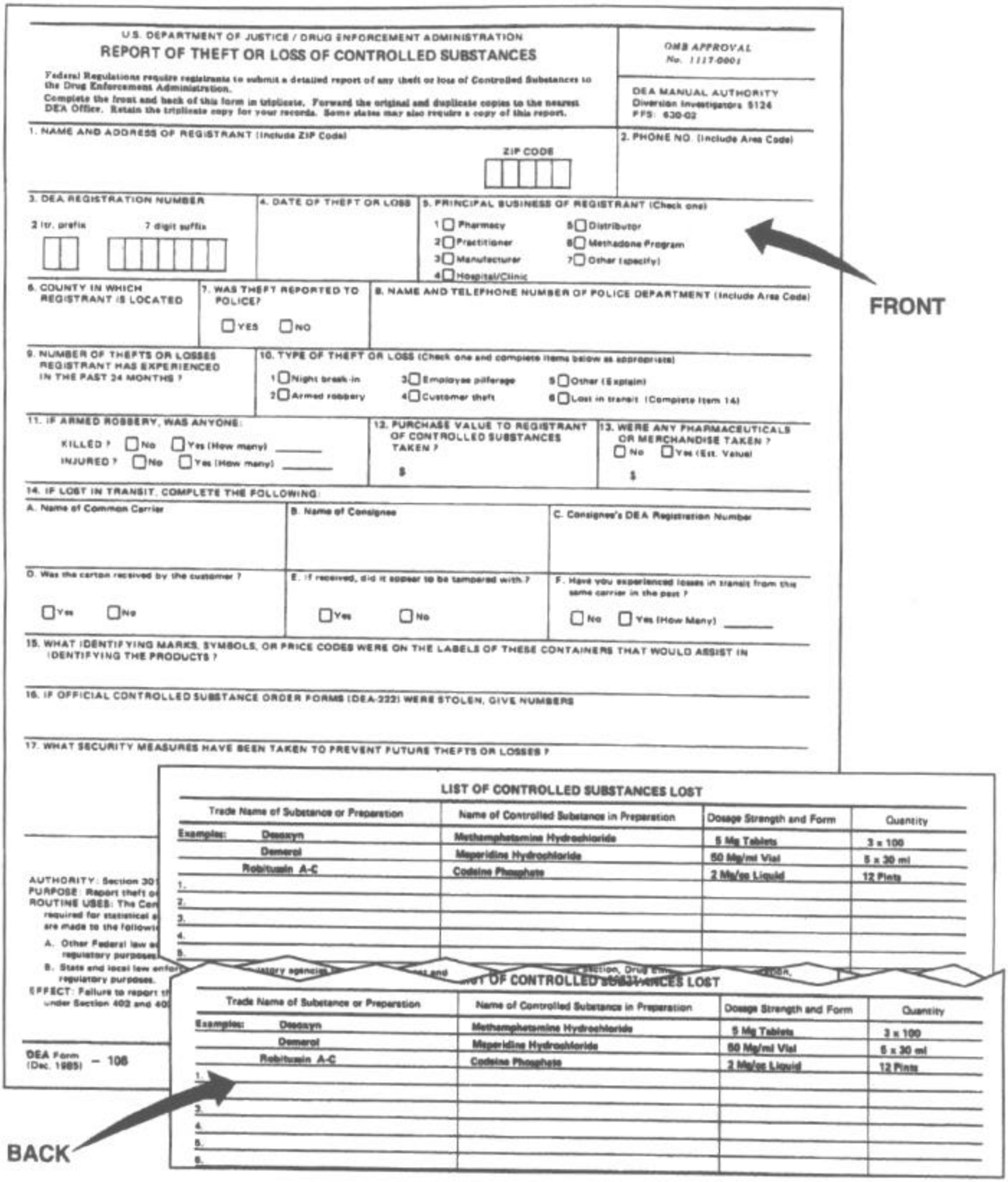
1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance content of each unit [illegible] in column 3; e.g., morphine sulfate tabs., 3 pkgs., 100 tabs., [illegible] gr. (16 mg.) or morphine sulfate tabs., 1 pkg., 83 tabs., 1/2 gr. ([illegible]

2. All [illegible] a single [illegible] name, [illegible]

Exhibit 5.6: DEA Form 41

5.7.3 Code T: Theft

Transaction code T is used to report controlled substances ***stolen from your premises***. This does not eliminate the requirement to prepare an official theft report, U.S. Department of Justice, Drug Enforcement Administration, Report of Theft or Loss of Controlled Substances, DEA Form 106. Contact your local DEA office for further details. See Section 5.8.3 Code X, for in-transit theft or loss. Exhibit 5.7: DEA Form 106, contains a sample theft report form.



U.S. DEPARTMENT OF JUSTICE / DRUG ENFORCEMENT ADMINISTRATION

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

OMB APPROVAL No. 1117-0001

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration.
Complete the front and back of this form in triplicate. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

DEA MANUAL AUTHORITY
Diversion Investigators 5124
FFS: 630-02

1. NAME AND ADDRESS OF REGISTRANT (Include ZIP Code)

ZIP CODE

2. PHONE NO. (Include Area Code)

3. DEA REGISTRATION NUMBER
2 ltr. prefix 7 digit suffix

4. DATE OF THEFT OR LOSS

5. PRINCIPAL BUSINESS OF REGISTRANT (Check one)
1 ☐ Pharmacy 5 ☐ Distributor
2 ☐ Practitioner 6 ☐ Methadone Program
3 ☐ Manufacturer 7 ☐ Other (specify)
4 ☐ Hospital/Clinic

6. COUNTY IN WHICH REGISTRANT IS LOCATED

7. WAS THEFT REPORTED TO POLICE?
☐ YES ☐ NO

8. NAME AND TELEPHONE NUMBER OF POLICE DEPARTMENT (Include Area Code)

9. NUMBER OF THEFTS OR LOSSES REGISTRANT HAS EXPERIENCED IN THE PAST 24 MONTHS ?

10. TYPE OF THEFT OR LOSS (Check one and complete items below as appropriate)
1 ☐ Night break-in 3 ☐ Employee pilferage 5 ☐ Other (Explain)
2 ☐ Armed robbery 4 ☐ Customer theft 6 ☐ Lost in transit (Complete item 14)

11. IF ARMED ROBBERY, WAS ANYONE:
KILLED ? ☐ No ☐ Yes (How many) _____
INJURED ? ☐ No ☐ Yes (How many) _____

12. PURCHASE VALUE TO REGISTRANT OF CONTROLLED SUBSTANCES TAKEN ?
$

13. WERE ANY PHARMACEUTICALS OR MERCHANDISE TAKEN ?
☐ No ☐ Yes (Est. Value)
$

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier

B. Name of Consignee

C. Consignee's DEA Registration Number

D. Was the carton received by the customer ?
☐ Yes ☐ No

E. If received, did it appear to be tampered with ?
☐ Yes ☐ No

F. Have you experienced losses in transit from this same carrier in the past ?
☐ No ☐ Yes (How Many) _____

15. WHAT IDENTIFYING MARKS, SYMBOLS, OR PRICE CODES WERE ON THE LABELS OF THESE CONTAINERS THAT WOULD ASSIST IN IDENTIFYING THE PRODUCTS ?

16. IF OFFICIAL CONTROLLED SUBSTANCE ORDER FORMS (DEA-222) WERE STOLEN, GIVE NUMBERS

17. WHAT SECURITY MEASURES HAVE BEEN TAKEN TO PREVENT FUTURE THEFTS OR LOSSES ?

AUTHORITY: Section 30
PURPOSE: Report theft o
ROUTINE USES: The Cor
required for statistical a
are made to the followi
A. Other Federal law e
regulatory purposes.
B. State and local law enfor
regulatory purposes.
EFFECT: Failure to report t
under Section 402 and 40

DEA Form (Dec. 1985) – 106

FRONT

LIST OF CONTROLLED SUBSTANCES LOST

Trade Name of Substance or Preparation	Name of Controlled Substance in Preparation	Dosage Strength and Form	Quantity
Examples: Dexoxyn	Methamphetamine Hydrochloride	5 Mg Tablets	3 x 100
Demerol	Meperidine Hydrochloride	50 Mg/ml Vial	5 x 30 ml
Robitussin A-C	Codeine Phosphate	2 Mg/oz Liquid	12 Pints
1.			
2.			
3.			
4.			
5.			

LIST OF CONTROLLED SUBSTANCES LOST

Trade Name of Substance or Preparation	Name of Controlled Substance in Preparation	Dosage Strength and Form	Quantity
Examples: Dexoxyn	Methamphetamine Hydrochloride	5 Mg Tablets	3 x 100
Demerol	Meperidine Hydrochloride	50 Mg/ml Vial	5 x 30 ml
Robitussin A-C	Codeine Phosphate	2 Mg/oz Liquid	12 Pints
1.			
2.			
3.			
4.			
5.			
6.			

BACK

Exhibit 5.7: DEA Form 106

5.7.4 Code Z: Receipt by Government or Seizures

Transaction code Z is used to report the transfer (e.g., samples or seizure) of reportable controlled substances from a manufacturer or distributor to a government official.
When a controlled substance is received by an agent of DEA or FDA, the DEA registration number of their Area Office must be entered in the *associate registrant number* field (Field 7). "**OFFICER**" is the entry in Field 7 for any other non-registered government official such as a customs officer; an agent of the Bureau of Alcohol, Tobacco, and Firearms; or state and local police officers. This entry ***must be*** in all ***capital letters*** and ***left justified*** within Field 7.

5.7.5 Manufacturing Disposition Codes

The following disposition transaction codes are discussed in Section 6, Manufacturing Activities:

transaction code N	Nonrecoverable Waste (Manufacturers Only)
transaction code U	Used in Production (Manufacturers Only)
transaction code Q	Sampling (Manufacturers Only)
transaction code K	Used In Preparations (Manufacturers Only)

5.8 MISCELLANEOUS TRANSACTION CODES

5.8.1 Code 7: No ARCOS Activity for the Current Reporting Period

Transaction code 7 is used to report the lack of controlled substance activity for the ***current*** reporting period. This ***lack*** of activity ***must be reported*** to DEA (ARCOS). *transaction code 7* is used when there has been ***no business activity for any and all*** controlled substances during the reporting period. It is not necessary to report no (i.e., zero) activity for each NDC product; a single *transaction code 7* will suffice. Submitting a *transaction code 7* will prevent DEA from placing the ARCOS Registrant in a delinquent reporting status. *Transaction code 7* requires the following fields:

- *reporting registration number*
- *transaction code 7*
- *transaction date* (last day of the *reporting period*)
- *transaction identifier*

5.8.2 Code F: Reorder DEA Form 333

Transaction code F is used to re-order a supply of DEA Form 333. The quantity requested cannot exceed 500 sheets for any single re-order. When the *quantity* field (Field 5) is left blank 100 forms will be sent. Complete only the following fields:

Field 1: *reporting registrant number*
Field 2: *transaction code F*
Field 5: *quantity*
Field 14: *transaction identifier*

5.8.3 Code X: Lost-in-Transit

Transaction code X is used by the seller to report the loss or theft of an in-transit shipment of a reportable controlled substance. It is reported ***in addition*** to the normal sales transaction (*transaction code S*). *Transaction code X* is an ***explanatory*** transaction code which does ***not*** affect an ARCOS registrant's inventory. Enter the DEA registration number of the intended purchaser in the *associate registrant number* field (Field 7). If the product lost in transit was a Schedule I or II controlled substance the selling ARCOS registrant ***must*** file an official theft report, U.S. Department of Justice, Drug Enforcement Administration, Report of Theft or Loss of Controlled Substances, DEA Form 106, with the local DEA office. Exhibit 5.7: DEA Form 106, contains a sample theft report form. If the ARCOS registrant purchasing the product still wants it, this registrant ***must*** supply a ***new*** order form with a ***new*** DEA order form number to ***replace*** the original one.

5.9 ACTION INDICATOR (Formerly DELETE INDICATOR)

5.9.1 Definition: Action Indicator

The *action indicator* was formerly called the *delete indicator*. The name has been changed to reflect the fact that the function of this field has been expanded.

The *action indicator* is a single-character field which initiates three different ARCOS data base operations: (1) the deletion of a *transaction record*, (2) the revision (adjustment) of ***data*** in a *transaction record*, and (3) the insertion of a late *transaction record*. These three data base operations are components of ARCOS error processing. Section 7.5, Correcting Transaction Records, contains a full discussion of the error processing.

5.9.2 Specifications: Action Indicator

a. Field Number: 3
b. Field Name: *action indicator* (Formerly *delete indicator*)
c. Field Length: 1 Character
d. Position/Column: 11
e. Type: Alphabetic
f. Special Rules:
   1. Code "D" to delete a *transaction record*
   2. Code "A" to adjust (revise) ***data*** in a *transaction record*
   3. Code "I" to insert (add) a late *transaction record*
   4. Use only capital letters
   5. Leave blank when unused

5.9.3 Discussion: Action Indicator

See Section 7.5, Correcting Transaction Records for additional *action indicator* instructions.

5.10 NATIONAL DRUG CODE (NDC)

5.10.1 Definition: NDC

The National Drug Code (NDC) used by ARCOS is an 11-character code that identifies controlled substance products. This code is divided into three segments: the labeler code, the product code, and the package size code. General specifications are presented in Section 5.10.2, Specifications: NDC, followed by detailed specifications for each segment.

5.10.2 Specifications: NDC

a. Field Number: 4
b. Field Name: NDC Number
c. Field Length: 11 Characters
d. Positions/Columns: 12-22
e. Type: Alphanumeric
f. Special Rules:
   1. Always coded except for *transaction codes 7, 8, and F*.
   2. Entries must be made in each segment (Labeler Code, Product Code, Package Size Code).

3. Do ***not*** use hyphens (-), slashes (/), or blanks.
4. Do ***not*** enter product's name in lieu of the NDC.
5. Use capital letters for alphabetic data
6. See specific segment for additional special rules.

5.10.2.1 NDC Segment Specifications

Labeler Code

The National Drug Code Directory[1] defines a labeler as "...any firm that manufactures or distributes a drug product." The labeler code is assigned by the FDA.

a. Segment Name: Labeler Code
b. Field Length: 5 Characters
c. Positions/Columns: 12-16
d. Type: Alphanumeric
e. Special Rules:
    1. Right justified.
    2. Leading zeros ***must*** be entered to fill blank segment positions or columns.

Product Code

The National Drug Code Directory defines the product code as the segment that "identifies a specific strength, dosage form, and formulation for a particular labeler." The product code is assigned by the labeler.

a. Segment Name: Product Code
b. Field Length: 4 Characters
c. Positions/Columns: 17-20
d. Type: Alphanumeric
e. Special Rules:
    1. Right justified.
    2. Leading zeros ***must*** be entered to fill blank segment positions or columns.

[1] U.S. Department of Health and Human Services, Food and Drug Administration, *National Drug Code Directory*, Vol I, June 1995.

Package Size Code

The National Drug Code Directory defines package size code as the segment that "identifies trade package sizes." The package size code is assigned by the labeler.

a. Segment Name: Package Size Code
b. Field Length: 2 Characters
c. Positions/Columns: 21-22
d. Type: Alphanumeric or "**" for bulk finished (e.g., unpackaged bulk dosage units) or bulk raw material (e.g., powder or liquid)
e. Special Rules:
    1. Right justified.
    2. Leading zeros ***must*** be entered to fill blank segment positions or columns.

5.10.2.2 Formatting Summary

Exhibit 5.8: NDC Formatting Summary, briefly describes the formatting specifications for the NDC. These specifications apply to controlled substance transactions reported on automated media as well as DEA Form 333 for the following products:

a. Bulk Raw Powder
b. Bulk Dosage Formulations
c. Bulk Solutions
d. Trade Packages

TYPE OF MATERIAL	LABELER CODE POSITIONS or COLUMNS: 12-16	PRODUCT CODE POSITIONS or COLUMNS: 17-20	PACKAGE CODE POSITIONS or COLUMNS: 21-22
Bulk raw powder; bulk dosage forms; bulk solutions	alphanumeric, right justified, fill blanks with leading zeros	alphanumeric, right justified, fill blanks with leading zeros	**
Trade Packages	alphanumeric, right justified, fill blanks with leading zeros	alphanumeric, right justified, fill blanks with leading zeros	alphanumeric, right justified, fill blanks with leading zeros

Exhibit 5.8: NDC Formatting Summary

5.10.3 NDC Coding Examples

The NDC configuration for ARCOS reporting is composed of a 5-character Labeler Code, a 4-character Product Code, and a 2-character Package Code. When the NDC for a product ***does not*** conform to the configuration required under ARCOS, the following changes ***must*** be made in the configuration:

a. A leading zero ***must*** be added to the Labeler Code when this segment contains 4-characters.

b. A leading zero ***must*** be added to the Product Code when this segment contains 3-characters.

c. A leading zero ***must*** be added to the Package Size Code when this segment contains 1-character.

d. "**" ***must*** be placed in the Package Size Code segment when the product ***does not*** have a Package Size Code. The "**" indicates the product is in bulk form.

Transactions with incorrectly formatted NDC fields are rejected as erroneous and must be corrected and resubmitted. The exhibits in this section illustrate correct coding for the NDC field. Exhibit 5.9: Converting the NDC for a Non-bulk Product, illustrates how to convert an NDC for a non-bulk product to the format required by ARCOS. Exhibit 5.10: Converting the NDC for a Bulk Product, illustrates how to convert an NDC for
a bulk product to the ARCOS format.

Fictitious Non-bulk Product (NDC Directory Configurations):

(a) 1234 - 1234 - 12 (b) 12345 - 123 - 34 (c) 12345 - 1234 - 7

Converting To ARCOS NDC Configurations

a. 01234 - 1234 - 12
↑_____leading zero added

b. 12345 - 0123 - 34
↑_____leading zero added

c. 12345 - 1234 - 07
↑_____leading zero added

Exhibit 5.9: Converting the NDC for a Non-bulk Product

Fictitious Bulk Product (NDC Directory Configurations):

(a) 1234 - 1234 (b) 12345 - 123 (c) 12345 - 1234

Converting To ARCOS NDC Configurations

a. 01234 - 1234 - **
↑___"**"added
↑_____ leading zero added

b. 12345 - 0123 - **
↑___"**"added
↑_____ leading zero added

c. 12345 - 1234 - **
↑___"**"added

Exhibit 5.10: Converting the NDC for a Bulk Product

5.10.4 NDC Assignment

Identification of reportable controlled substances is always based on the Food and Drug Administration's National Drug Code (NDC). ***All*** *transaction records*, ***except*** for transaction codes 7, 8, and F ***must*** contain an NDC. Any *transaction record* with missing or invalid NDC will be rejected and must be corrected before being resubmitted. Contact the FDA at the address provided in Exhibit 5.11: FDA Address, for information about the National Drug Code.

Food and Drug Administration
Bureau of Drugs, Drug Listing Staff
5600 Fishers Lane
Center for Drug Evaluation & Research (CDER), HFD-95
Rockville, Maryland 20857
Telephone: (301) 594-1086 Hours: Monday-Friday 8:00am - 4:30pm EST/EDT

Exhibit 5.11: FDA Address

5.10.5 Submitting Labels

Pursuant to 21 CFR 1308.04, firms holding a DEA registration as a manufacturer ***must*** provide DEA (ARCOS) with information about each new product, new dosage form, or other unit form containing ***any*** quantity of controlled substance. This information ***must*** be submitted within 30 days ***after*** manufacturing begins. However, DEA (ARCOS) will also accept this information ***prior to*** the beginning of manufacturing. Two labels or other documents (e.g., Drug Listing Form, FDA 2657) which reflect the following information ***must*** be submitted:

a. The trade name, brand name, or other commercial name of the product;

b. The generic or chemical name and quantity of each active ingredient, including both controlled and non-controlled substances (indicate what information is a proprietary trade secret);

c. The National Drug Code assigned to the product, if any; and

d. The weight of controlled substance as follows:
(1) Finished Dosage Unit Products:
Grams or milligrams per dosage unit
(2) Bulk Products:
Grams or milligrams per gram of powder
Grams or milligrams per milliliter of liquid

Send this information to DEA (ARCOS). The address is listed on the contact information page at the front of this handbook. The Data Systems Unit (ARCOS)

strongly advises each manufacturer to send this information ***before*** submitting *transaction records* for their new products. A *transaction record* that does not have a matching NDC in the ARCOS NDC Dictionary is rejected as erroneous and must be resubmitted. Call the Data Systems Unit (ARCOS) to find out if the NDC information for your firm's new product has been added to the Dictionary.

All transactions for the new product that have occurred ***before*** the current reporting period, ***must*** be submitted as ***Late Transactions***. Otherwise, these transactions will be rejected as errors because their *transaction dates* are ***not*** within the current reporting period. See Section 7, Edit Listings, for Late Transaction instructions.

5.10.6 Pseudo NDC's

The pseudo NDC is a number developed by DEA (ARCOS) in consultation with the ARCOS registrant. A pseudo NDC may be requested from the DATA Systems Unit (ARCOS) when the NDC does not exist or is unavailable. This number enables ARCOS registrants to report transactions involving products for which an NDC is either unavailable or does not exist. Pseudo NDC's are ***not*** listed in the Food and Drug Administration's National Drug Code Directory.

5.10.6.1 Obtaining a Pseudo NDC

A written request on company letterhead must be made to the Data Systems Unit (ARCOS) for ***each*** product for which a pseudo NDC is needed. The request may be sent by mail or fax to the address or fax phone number listed on the contact information page at the front of the handbook and ***must*** contain the following information:

a. Manufacturer's Name and Address
b. Product Name and/or Generic Chemical Name
c. CSA Schedule and Drug Code
d. Controlled Ingredients and Concentration of Controlled Ingredients
e. Whether Controlled Ingredient is in Base or Salt Form
f. Package Size
g. Molecular Weight, Chemical Formula and Structure of Controlled Substance, if available.

5.10.7 Inner and Outer NDC Packages

A controlled substance product may have one NDC on an outer, larger package and a different NDC on the inner, smaller, individually-packaged units contained within the larger package. See Exhibit 5.12: Inner and Outer Packaging for an illustration. Either NDC may be used when reporting transactions and inventories. Care must be taken that the NDC ***corresponds*** to the product and package size being reported. A single NDC ***must never*** be used to identify two different package sizes of a product. The quantity reported will indicate the number of packages for that particular NDC.

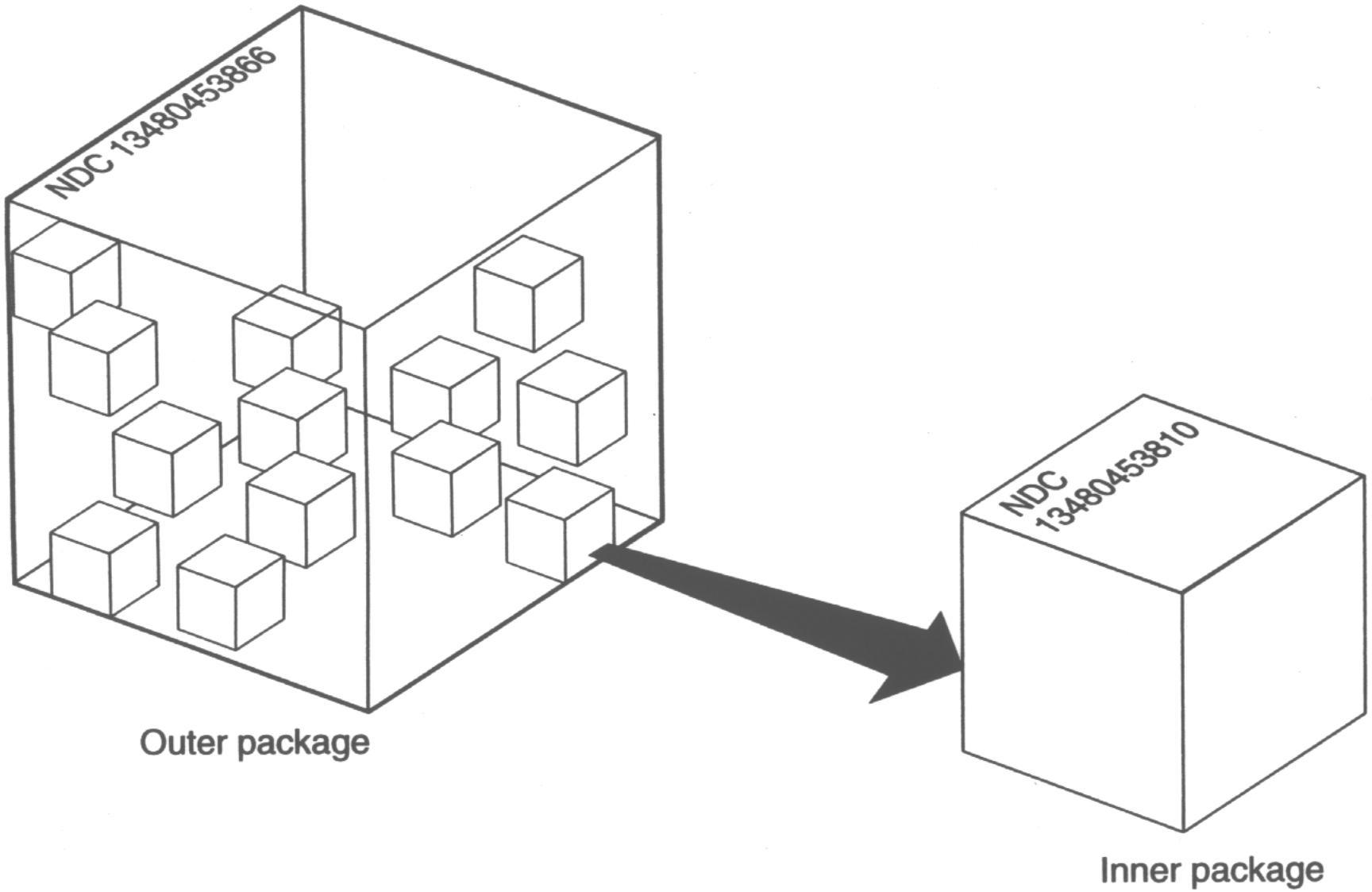


Exhibit 5.12: Inner and Outer Packages

5.11 QUANTITY

5.11.1 Definition: Quantity

The *quantity* field is a 6-digit (manual) or 8-digit (automated) numeric field containing the number of packages, weight, or volume being reported.

5.11.2 Specifications: Quantity

a. Field Number: 5
b. Field Name: *quantity*
c. Field Length: 8 digits (automated)
6 digits (manual)
d. Positions/Columns: 23-30 (automated)
23-28 (manual)
e. Type: Numeric
f. Special Rules:

1. Mandatory entry, except for *transaction codes 7, 8, and F*.
Note: For *transaction code F* 100 forms will be sent when the *quantity* field is left blank.

2. *Quantity* field (Field 5) and *unit* field (Field 6) are mandatory entries when the controlled substance is measured in weight or volume.

3. When the *unit* field is blank, the quantity entered corresponds to the number of packages being reported.

4. Right justify entry.

5. Blanks are ***not*** permitted. Insert leading zeros in columns to the left of the number entered.

6. Enter whole numbers only. Do not truncate. Do not round. Do not use decimals, commas, etc.

5.11.3 Discussion: Quantity

5.11.3.1 Converting Fractional (Decimal) Quantities

All quantities ***must*** be reported in whole numbers that have neither been truncated nor rounded. To report a fractional quantity, convert the amount to units that do not require fractions. For example, to report a bulk quantity of 417.29 grams, the quantity must be converted to milligrams prior to being reported (i.e., 417.29 grams would be reported as a quantity of "417290" with a *Unit* Code of 2 which indicates milligrams. The following examples illustrate the correct coding of fractional quantities for both automated and manual reports:

Automated Report (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)        (4)            (5)      (6)       (7)          (8)          (9)    (10) (11)     (12)      (13)
PP1234567   S       001790062**  00417290   2    AB1234567 940590027   012194      1000 000000001 E25
```

Manual Report (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)        (4)            (5)      (6)       (7)          (8)          (9) (10)     (11-13)     (14)
PP1234567   S       001790062**  417290     2    AB1234567 940590027          1000     40121      00002
```

5.11.3.2 Coding the Quantity Field

Exhibit 5.13: Quantity Field Entries, illustrates *quantity* field coding.

NDC Number	PACKAGE DESCRIPTION	QUANTITY FIELD ENTRY	DESCRIPTION OF ITEM(S) REPORTED
99999-9999-**	Bulk Tablets	00025000	25,000 Tablets
88888-8888-01	Bottle of 500 Tablets	00000001	1 bottle of 500 Tablets
88888-8888-01	Bottle of 500 Tablets	00000005	5 bottles * 500 Tablets/bottle
77777-7777-04	4 fl oz Bottle	00000001	1 bottle of 4 fl oz
77777-7777-04	4 fl oz Bottle	00000003	3 bottles of 4 fl oz each (total=12 fl oz)
66666-6666-01	5ml Ampule (injection)	00000001	5 ml
66666-6666-01	5ml Ampule (injection)	00000005	5 ampules of 5 ml each (total = 25 ml)
55555-5555-02	Box of 10 each 5ml Ampules (injection)	00000001	1 box (50ml)
55555-5555-02	Box of 10 each 5ml Ampules (injection)	00000010	10 boxes (500ml) 500 ml in 10 boxes of 50 ml each

Exhibit 5.13: Quantity Field Entries

Appendix 4, Use of Quantity, Unit, and Strength Fields, contains additional examples of the relationships between various types of products (e.g., bulk raw powder, bulk dosage units, trade packages) and the *quantity*, *unit*, and *strength* fields in the ARCOS *transaction record*.

5.11.3.3 Reporting Bulk Raw Material

The *unit* (Field 6) and *strength* (Field 11 automated, Field 10 manual) fields must always be completed when reporting a Bulk Raw Material (package code = **) by weight or volume. See example below:

Example:

A manufacturer reports the synthesis (production) of a Schedule II bulk drug in raw powder form, 100 % pure. This product is chemically identified as Ecgonine Hydrochloride, molecular weight 221.69, NDC designation 00179-0062-**. The manufacturer sells 3,365.45gms of the product to another ARCOS registrant on January 21, 1997 under DEA order form number 940590027. The following example illustrates the coding for this transaction.

Automated Report: (numbers in parenthesis indicate data field numbers)

```
    (1)       (2) (3)       (4)             (5)     (6)       (7)          (8)          (9)    (10) (11)      (12)      (13)
PP1234567   S       001790062**    03365450  2    AB1234567  940590027    012197        1000  000000001  E25
```

Note: Reported as milligrams

Manual Report: (numbers in parenthesis indicate data field numbers)

```
    (1)       (2) (3)       (4)             (5)     (6)       (7)          (8)          (9)    (10)      (11-13)      (14)
PP1234567   S       001790062**    003365   3    AB1234567  940590027          1000       70121     00001
PP1234567   S       001790062**    000450   2    AB1234567  940590027          1000       70121     00002
```

5.11.3.4 Reporting Bulk Dosage Form Material

When a finished bulk item (e.g., drum of capsules or tablets) is reported, it is typically assigned a double asterisk (**) for its NDC package code. The *quantity* field contains the total number of bulk dosage units being reported. See example below:

Example:

Manufacturer reports the production of large quantities of capsules, each capsule contains 10mg of Schedule II d-amphetamine hydrochloride, molecular weight 171.67, NDC designation 00023-0124-**. Manufacturer sells 865,400 capsules to another ARCOS Registrant on May 22, 1997 under DEA order form number 940079038. The coding example for this transaction is illustrated below.

Automated Report (numbers in parenthesis indicate data field numbers)

```
    (1)       (2) (3)       (4)             (5)     (6)       (7)          (8)          (9)    (10) (11)      (12)      (13)
PP1234567   S       000230124**    00865400        AB1234567  940079038  052297              000000001  E25
```

Manual Report (numbers in parenthesis indicate data field numbers)

```
    (1)       (2) (3)       (4)             (5)     (6)       (7)          (8)          (9)    (10) (11-13)      (14)
PP1234567   S       000230124**    865400          AB1234567  940079038                70522     00001
```

5.12 UNIT CODE

5.12.1 Definition: Unit Code

The *unit code* is a single-character, alphanumeric field used in conjunction with the *quantity* and *strength* fields to specify, by weight or volume, the amount of an NDC product being reported.

5.12.2 Specifications: Unit Code

a. Field Number: 6
b. Field Name: *unit* code
c. Field Length: 1 Character
d. Position/Column: 31 (Automated)
29 (Manual)
e. Type: Alphanumeric
f. Special Rules:

1. Must be completed for all substances reported by weight or volume.

2. May also be used to modify the *Quantity* field by indicating dozens or thousands of packages.

5.12.3 Weight and Volume Unit Codes

The *unit code* field must be completed for all transactions reported by weight or volume by entering one of the following unit codes:

1 = micrograms
2 = milligrams
3 = grams
4 = kilograms
5 = milliliters
6 = liters

5.12.4 Optional Unit Codes

Transaction records reporting NDCs that consist of complete package or dosage units ***do not*** require a unit code. However, the following ***optional*** unit codes may be used to report dozens or thousands of packages or dosage units.

a. D = Dozens:
"D" indicates that the entry in the *quantity* field (Field 5) represents dozens of packages or dozens of dosage units.

b. K = Thousands:
"K" indicates that the entry in the *quantity* field (Field 5) represents thousands of packages or thousands of dosage units.

Example:

A sale of 10,000 units can be reported with a number 10 in the *quantity* field (Field 5) and a "K" in the *unit code* field (Field 6) as follows:

Automated Report: (numbers in parenthesis indicate data field numbers)

```
     (1)      (2) (3)       (4)             (5)      (6)       (7)           (8)           (9)    (10) (11)      (12)       (13)
PP1234567  S      00065126810  00000010  K   AB1234567  940069028    081594              000000001   E25
```

Manual Report: (numbers in parenthesis indicate data field numbers)

```
     (1)      (2) (3)       (4)             (5)      (6)       (7)           (8)           (9)    (10)  (11-13)    (14)
 PP1234567  S      00065126810   000010    K   AB1234567  940069028                      40815    00001
```

Appendix 4, Use of Quantity, Unit, and Strength Fields, contains additional examples of how to use *quantity*, *unit code*, and *strength* fields to report transactions involving NDC products in various forms, (e.g., bulk raw powder, bulk dosage units, trade packages).

5.13 ASSOCIATE REGISTRANT NUMBER

5.13.1 Definition: Associate Registrant Number

The *associate registrant number* is a 9-character field identifying the customer or supplier with which the transaction took place. For a sale enter the DEA registration number of the customer. For a purchase enter the DEA registration number of the supplier. Note: This field is labeled "Associate Registration Number" on DEA Form 333.

5.13.2 Specifications: Associate Registrant Number

a. Field Number: 7
b. Field Name: *associate registrant number*
c. Field Length: 9 Characters
d. Positions/Columns: 32-40 (Automated)
30-38 (Manual)
e. Type: Alphanumeric
f. Special Rules:
1. Use only DEA registration numbers.
2. Do not enter registrant's name.
3. Use only capital letters for alphabetic entries.

5.13.3 Discussion: Associate Registrant Number

The associate registrant number is required for ***each*** transaction that increases or decreases the ARCOS registrant's inventory. The reporting registrant number and the associate registrant number ***cannot*** be the same. The *associate registrant number* field is ***not*** completed when reporting the following transaction codes:

Schedule Change Inventory	Code 1
Year-end Inventory	Code 3
Year-end In-process Inventory	Code 4
Special Inventory	Code 5
No Year-end Inventory	Code 8
No Activity	Code 7
Forms Request	Code F
Thefts	Code T
Manufacturing Transaction Codes:	M, W, L, J, N, U, K and Q.

5.13.3.1 Transfers to Exempt Organizations

Organizations which are exempt from registration with DEA under the Controlled Substances Act may acquire products containing controlled substances from an ARCOS registrant. When an ARCOS registrant provides an exempt organization with such a product, the registrant reports this transaction by entering one of the codes listed in Exhibit 5.14: Exempt Organization Codes, in the *associate registrant number* field, Field 7. All entries ***must*** be ***left justified*** and in ***all capital (upper case) letters.*** Any remaining positions or columns ***must*** be blank.

Exempt Organization	Entry in Field 7 (Left Justified)
Civil Defense Officials	CIVILDEF
FDA or DEA Drug Recall	RECALL
Law Enforcement Official	OFFICER
Ocean Vessels Receiving Controlled Substances	VESSELS
Native American Church	NATIVE
Military, Public Health Service, Bureau of Prisons, or Coast Guard	MILITARY

Exhibit 5.14: Exempt Organization Codes

5.13.3.2 Transfers Within a Firm

The transfer of a controlled substance from one DEA registration to another ***within*** the ***same firm***, ***must*** be treated as a normal sale (*transaction code S*) and purchase (*transaction code P*). For example, when a transfer from a manufacturer's inventory to a distributor's inventory takes place, two transactions are reported:

a. A sale (*transaction code S*) is reported under the manufacturing registration number. The distributor's DEA registration number is entered into the *associate registrant number* field (Field 7).

b. A purchase (*transaction code P*) is reported under the distributor's registration number. The manufacturer's DEA registration number is entered into the *associate registrant number* field (Field 7).

5.13.3.3 Destruction of Reportable Items

Enter the registration number of the DEA area office in the *associate registrant number* field when reporting all destructions of controlled substances (*transaction code Y*. If necessary, contact the DEA area office or the Data Systems Unit (ARCOS) to obtain the DEA registration number. DEA Form 41, Registrants Inventory of Drugs Surrendered, ***must*** be completed and filed with the local DEA area office. Exhibit 5.6: DEA Form 41, contains a sample form.

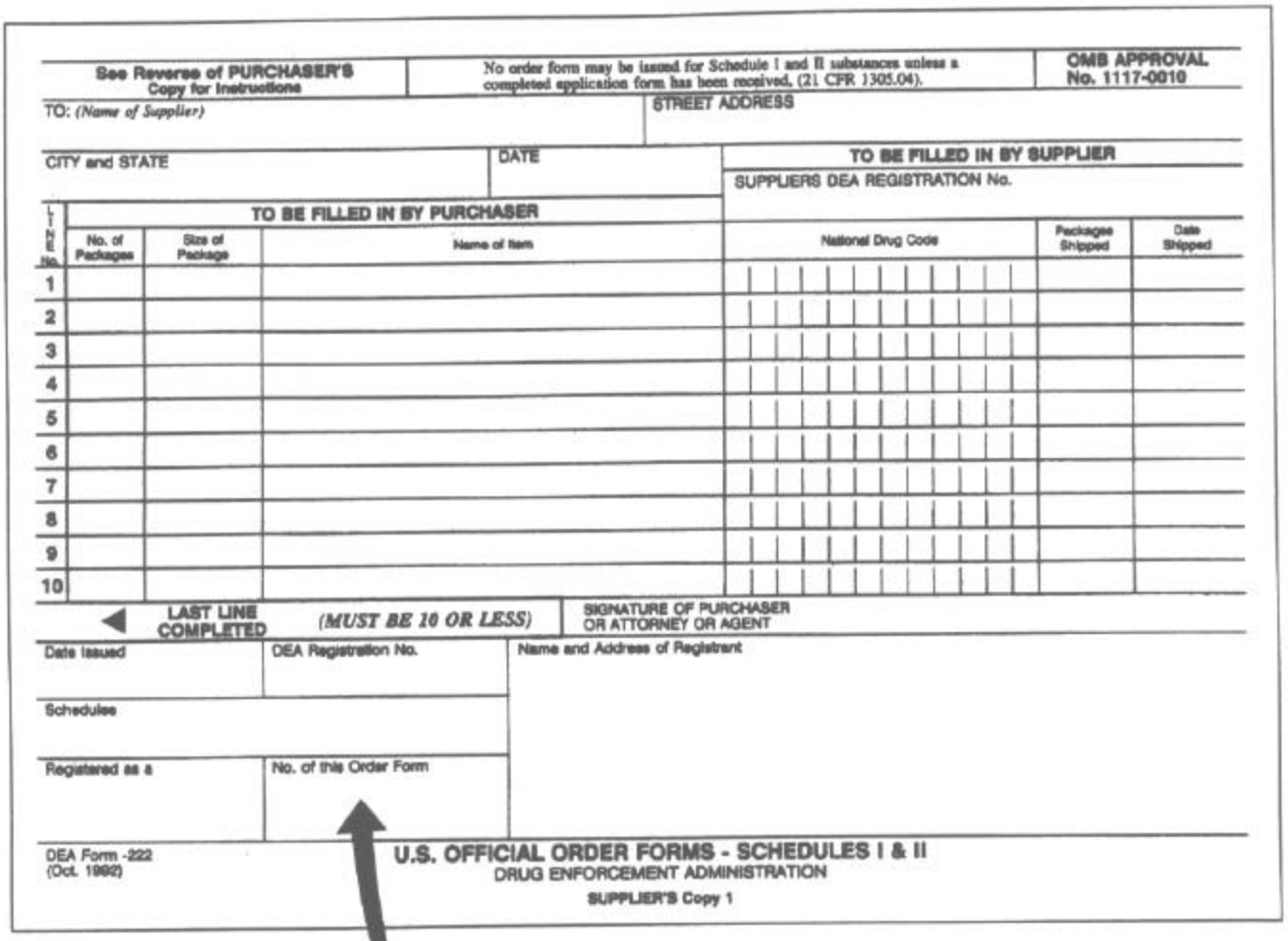
5.14 DEA ORDER FORM NUMBER

5.14.1 Definition: Order Form Number

The *DEA order form number* field is a 9-character field in which the number of the order form (DEA Form 222) is entered. This field is used only when Schedules I and II controlled substances are transferred. An order form is illustrated in Exhibit 5.15: DEA Form 222.

5.14.2 Specifications: Order Form Number

a. Field Number: 8
b. Field Name: *DEA order form number*
c. Field Length: 9 Characters
d. Positions/Columns: 41-49 (Automated)
39-47 (Manual)
e. Type: Alphanumeric
f. Special Rules:
    1. Mandatory for Schedules I and II
    2. Use Only Capital Letters for Alphabetic Data.



See Reverse of PURCHASER'S Copy for Instructions

No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).

OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)*

STREET ADDRESS

CITY and STATE

DATE

TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT

Date Issued

DEA Registration No.

Name and Address of Registrant

Schedules

Registered as a

No. of this Order Form

DEA Form -222 (Oct. 1992)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

DRUG ENFORCEMENT ADMINISTRATION

SUPPLIER'S Copy 1

Contains the number used in the DEA Order Form Number field (Field 8) of the ARCOS transaction record.

Exhibit 5.15: DEA Form 222

5.14.3 Discussion: Order Form Number

An order form, DEA Form 222, is required, pursuant to 21 CFR 1305, for transfers of Schedules I and II controlled substances, but an order form is ***not*** required for Schedule III narcotics. Leave the *DEA order form number* field blank when reporting Schedule 3 narcotics. Copy 2 of each DEA order form ***must*** be forwarded to the supplier's local DEA area office. Do ***not*** mail ***any*** copies of DEA Form 222 to DEA (ARCOS).

5.14.3.1 Manufacturer Recall

When a manufacturer recalls a reportable product, the transaction must be reported as a purchase (*transaction code P*). Those firms returning the product, that are also ARCOS registrants, report a sale (*transaction code S*). When a schedule I or II controlled substance is recalled, DEA, Office of Diversion Control, may grant a limited exemption to the requirement for order forms. When such an exemption has been granted, the *DEA order form number* field (Field 8), must be completed with the word ***"RECALL"*** in ***all capital letters, left justified***. The remainder of the field must contain ***blank spaces***.

5.15 TRANSACTION DATE

5.15.1 Definition: Transaction Date

The *transaction date* is the ***actual*** date on which a reportable activity occurred. Exceptions are covered in Section 5.15.4, Discussion.

5.15.2 Specifications: Transaction Date

a. Field Number	9 (automated) 11-13 (manual)
b. Field Name:	*transaction date*
c. Field Length:	6 digits (Automated) 5 digits (Manual)
d. Positions/Columns:	50-55 (Automated) 60-64 (Manual)
e. Type:	Numeric

f. Special Rules:

1. Automated and manual reporting have different formats.

5.15.3 Transaction Date Formats

Automated Format: **MMDDYY** (month, day, year)

Positions 50-51:	Month (01-12)
Positions 52-53:	Day (01-31)
Positions 54-55:	Year (last two-digits of the year 95, 96, etc.)

Coding Examples:

January 1, 1996:	010196
November 11, 1997:	111197

Manual Format: **YMMDD** (year, month, day)

Column 60:	Year (last digit of the year, 0-9)
Columns 61-62:	Month (01-12)
Columns 63-64:	Day (01-31)

Coding Examples:

January 1, 1996:	60101
November 11, 1997:	71111

5.15.4 Discussion: Transaction Date

A *transaction date* must be entered for all transactions. The *transaction date* ***must*** be the ***actual date*** on which the activity occurs. Except for manufacturing codes and delete, late, and adjustment transactions, the date of a transaction ***must never*** fall outside of the *reporting period* for the report being submitted.

Examples:

a. A *transaction record* with a June *transaction date* submitted with the July report is rejected unless it is a delete, late, or adjustment transaction (*action indicator* "D", "A", or "I").

b. Manufacturing activities associated with *transaction codes M, K, U, N, W, L, Q, and J* are reported as of the end of a quarter or the end of each year, even though these activities may actually have occurred on other dates during the year.

When using the duplicate sign (i.e. "=") to repeat a *transaction date* within a manual report, fields 11, 12 and 13 ***must*** be considered one field. In other words, the ***entire date must*** be the same when using the duplication sign. See Exhibit 5.2: Using the Duplicate Sign, Single Reporter or Exhibit 5.3: Using the Duplicate Sign, Central Reporter.

5.16 CORRECTION TRANSACTION

5.16.1 Definition: Correction Transaction

A Correction Transaction ***corrects*** a transaction that has been rejected by the data validation procedures. Rejected *transaction records* are listed in the Daily Transaction Processing Error Report.

5.16.2 Specifications: Correction Number (Formerly Lot Number)

a. Field Number: 10 (automated)
9 (manual)
b. Field Name: *correction number* (formerly lot number)
c. Field Length: 8 digits
d. Positions/Columns: 56-63 (Automated)
48-55 (Manual)
e. Type: Numeric
f. Special Rules:
1. Mandatory when submitting one or more Correction Transactions.

5.16.3 Discussion: Correction Number

Each Correction Transaction is identified by a unique, sequential *correction number*. The system uses this number when reprocessing the corrected *transaction record*. The *correction number* is listed on the error report and ***must*** be entered into the *correction number* field. The Correction Transaction is a component of ARCOS error processing. Section 7.5, Correcting Transaction Records, contains a full discussion of error processing including specific instructions for using the Correction Transaction.

5.17 STRENGTH

5.17.1 Definition: Strength

The *strength* field is used to report three different kinds of data: (1) the ***purity*** of a ***bulk raw*** material (2) the ***fractional portion*** of a standard NDC package size or (3) the ***percentage*** by which a package ***exceeds*** a standard NDC package size.

5.17.2 Specifications: Strength

a. Field Number: 11 (automated)
10 (manual)
b. Field Name: *strength*
c. Field Length: 4 Digits
d. Positions/Columns: 64-67 (Automated) 56-59 (Manual)
e. Type: Numeric
f. Special Rules:

1. Mandatory entry for both ***bulk raw*** material and ***partial*** packages.
2. Fractional or Excess Package Size:
   (a) Decimal is ***implied*** and ***never*** coded.
   (b) Implied decimal point:
   automated: between positions 66 & 67
   manual: between columns 58 & 59
   (c) Decimal position:
   automated: position 67
   manual: column 59

5.17.3 Discussion: Strength

5.17.3.1 Strength Field: Bulk Raw Materials

The *strength* field ***must*** be completed when reporting a bulk raw material. All bulk raw materials and their level of purity are initially entered into the ARCOS drug ingredient dictionary. A *strength* field entry of 1000 (i.e. 100.0% purity) in a transaction involving a bulk raw controlled substance product indicates that the purity of the product being reported is the same as the corresponding NDC bulk raw material listed in the ARCOS drug ingredient dictionary. The *strength* field is required when reporting bulk raw materials. Any entry different from 1000 in this field indicates that the material being reported has a different purity than the bulk NDC listed in the ARCOS drug ingredient dictionary.

Example 1:

An NDC for a bulk raw material containing controlled substance with 90% purity is listed in the drug ingredient dictionary. The manufacturer sells a quantity of this material, unaltered, to a distributor, i.e. the manufacturer sells a powder containing 90% of a reportable controlled substance. Both manufacturer and distributor report this transaction (a sale for the manufacturer and a purchase for the distributor) with an entry of 1000 in the *strength* field, indicating that the purity of the product reported is equal to that of the product listed in the drug ingredient dictionary.

Example 2:

The same manufacturer as above (example 1) makes a batch of the same controlled substance mentioned above, but this time the purity of the batch is only 81%. The manufacturer wishes to sell some of this 81% pure controlled substance product using the NDC that is based on 90% purity. In order to do this, the manufacturer enters 0900 in the *strength* field, indicating that the purity of the material being reported is 90.0% of the 90% purity of the bulk NDC listed in the drug ingredient dictionary (.900 x .90 = .81).

5.17.3.2 Strength Field: Partial Packages

A partial package is an NDC package that has been opened and contains less than its original contents. To report a transaction with a partial package, enter the entire NDC in the NDC field (Field 4). Enter 1 with the correct number of leading zeroes in the *quantity* field (Field 5). In the *strength* field, enter the number of thousandths of the original contents of the NDC package that are being reported.

Example:

An NDC represents a bottle containing 100 LAAM hydrochloride tablets. An ARCOS registrant has an opened bottle of this NDC with 90 tablets remaining, 90% of the original package contents. To report this partial package, enter 1 with leading zeroes in the *quantity* field (Field 5) and “0900" in the *strength* field (Field 11 automated, Field 10 manual). The entry “0900" in the *strength* field indicates 90.0%. The decimal point in this percentage is implied, it is not to be coded. The following illustrations depict the correct automated and manual coding for reporting this example.

ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

```
     (1)       (2) (3)       (4)           (5)      (6)      (7)           (8)          (9)     (10)  (11)      (12)       (13)
PP1234567   S      11326000301  00000001      AB1234567  940690028   081594       0900  00000001   E25
                                                                                                  ^------- Implied decimal
```

ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

```
     (1)       (2) (3)       (4)           (5)      (6)      (7)           (8)          (9)   (10)    (11-13)       (14)
PP1234567   S      11326000301   00000001      AB1234567  940690028          0900    40815       00001
                                                                                          ^------- Implied decimal
```

5.17.3.3 Strength Field: Combining Partial Packages

Two or more partial packages with the identical NDC may be reported as separate transactions or added together and reported as a single transaction, even when their combined contents are more than one complete package. The example below illustrates reporting ***two partial*** packages as a ***single*** transaction.

Example:

The standard NDC package size of Amytal tablets contains 100 tablets. An ARCOS Registrant needs to report two packages, each package containing less than 100 tablets. One package contains 90 Amytal tablets, while the other contains 25 Amytal tablets. The combined total of these two partial packages amounts to 115 tablets. This amount equals 115 percent of the standard package size.

To report 115 tablets as a single transaction, code a quantity of "1" in the *quantity* field (Field 5) and 1150 (115.0 percent of a full package) in the *strength* Field (Field 11 automated, Field 10 manual). Again, there is an ***implied*** decimal point between the two right-most positions in the *strength* Field.

ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

```
     (1)       (2) (3)       (4)           (5)      (6)      (7)           (8)          (9)     (10)  (11)      (12)       (13)
PP1234567   S      10465592001   00000001      AB1234567  940690028   081594       1150  00000001   E25
                                                                                                  ^------- Implied decimal
```

ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

```
     (1)       (2) (3)       (4)           (5)      (6)      (7)           (8)          (9)   (10)    (11-13)       (14)
PP1234567   S      10465592001   00000001      AB1234567  940690028          1150    40815       00001
                                                                                          ^--------- Implied decimal
```

Refer to Appendix 4, Use of Quantity, Unit, and Strength Fields, for additional illustrations of ARCOS reporting relationships between various types of NDC products (i.e., bulk raw powder, bulk dosage units, trade packages) and the (a) *quantity*, (b) *unit code*, and (c) *strength* data fields in the ARCOS *transaction record*.

5.18 TRANSACTION IDENTIFIER

5.18.1 Definition: Transaction Identifier

The *transaction identifier* is a sequential number assigned by the reporting registrant to each *transaction record*.

5.18.2 Specifications: Transaction Identifier

a. Field Number:	12 (automated) 14 (manual)
b. Field Name:	*transaction identifier*
c. Field Length:	10 digits (automated) 5 digits (Manual)
d. Positions/Columns:	68-77(Automated) 65-69 (Manual)
e. Type:	Numeric

f. Special Rules:

1. The first *transaction identifier* within each report **must always** begin with the number one (1).

2. Each *transaction record* in a reporting period ***must*** have a unique *transaction Identifier*.

3. Leading zeroes must be included.

4. The original *transaction identifier* is repeated when submitting a correction, an adjustment, or a deletion.

5. A Late Transaction uses the next sequential *transaction identifier* from the initial report submitted.

5.18.3 Discussion: Transaction Identifier

The *transaction identifier* field for *transaction records* submitted by central reporters may use one of two configurations:

a. Continuous Sequence:
Transaction records may be numbered in a continuous sequence.

b. Separate Sequences
Transaction records for each reporting registrant may be numbered in separate sequences.

Example: Continuous Sequence

A central reporter submits a report for itself and two subsidiaries containing a total of 150 transactions. These records may be numbered sequentially and continuously "1" through "150."

Example: Separate Sequences

A central reporter submits a report for itself and three subsidiaries containing a total of 400 transactions. These records may be numbered "1" to "125" for the central reporters own registration number, "1" to "50" for the first subsidiary, "1" to "200" for the second subsidiary and "1" to "25" for the third subsidiary.

5.19 DOCUMENT IDENTIFIER

5.19.1 Definition: Document Identifier

The *document identifier* is used to distinguish reports submitted on magnetic media (i.e., diskette or tape) from reports submitted on DEA Form 333 coding sheets. The *document identifier* appears only in automated *transaction records*.

5.19.2 Specifications: Document Identifier

a. Field Number: 13
b. Field Name: *document identifier*
c. Field Length: 3 Characters
d. Positions: 78-80
e. Type: Alphanumeric
f. Special Rules:
    1. "E25" is the only acceptable entry.
    2. Only in automated *transaction records*.

5.19.3 Discussion: Document Identifier

No additional discussion.

6

SECTION 6.0

MANUFACTURING ACTIVITIES

6.1 GENERAL

Section 6 contains ARCOS manufacturing instructions as they apply to the reporting of narcotics and psychotropics. The manufacturing activities and specific transaction code designations are identified and described in this section as follows: CODES 3, 4, W, M, L, J, K, Q, N, U. The narcotic and psychotropic drug statistics derived from these manufacturing transaction codes are used primarily for fulfillment of United States treaty obligations. The United States is a signatory to the (a) Single Convention on Narcotic Drugs, 1961 and (b) Convention on Psychotropic Substances, 1971, and as such is required to provide yearly statistics to the United Nations International Narcotics Control Board.

6.1.1 Reporting by Bulk and Dosage Form Manufacturers

Manufacturers of bulk powders, bulk dosage formulations and/or dosage package size formulations of any Schedule I & II controlled substance, any narcotic controlled substance in Schedule III, and any listed psychotropic controlled substances in Schedules III and IV must report those manufacturing activities as set forth in this section. The manufacturers of controlled substances in Schedules I and II and/or any narcotic in Schedule III are also required to report on those applicable transaction activities relating to inventories, acquisitions and dispositions as set forth in this handbook.

6.1.2 Reporting by Packers, Repackers and Relabelers

Manufacturers registered for activities such as packing, repacking and relabeling of controlled substances in Schedules I and II and/or any narcotic in Schedule III are not required to report

the actual packing, repacking or relabeling manufacturing activity, but must report other manufacturing activities as set forth in this section, as well as activities that relate to inventories, acquisitions, and dispositions as set forth in this handbook.

6.1.2.1 Definitions:

The following definitions are provided for clarification.

a. A packer/repacker is a registrant that packs a product into a container (i.e., packer) or repacks a product into different size containers, such as changing a package of 50 capsules to 5 packages of 10 capsules each (i.e., repacker).

b. A labeler/relabeler is a registrant that affixes the original label to a product (i.e., labeler) or changes in any way the labeling on a product without affecting the product or its container (i.e, relabeler). The "relabel" term implies that the package size remains unchanged with changes being made only in brand name, NDC number, distributor, etc. See the following example and reporting scenario:

6.1.2.2 Scenario for Repackaging and Relabeling

A manufacturer purchases 50,000 codeine phosphate tablets (NDC 00034-4156-**). The manufacturer subsequently repackages and relabels to package size of 50 per carton (NDC 00036-4156-01) and package size of 100 per carton (NDC 00036-4156-02). On June 23, 1997, 50 and 150 cartons of NDC products 00036-4156-01 and 00036-4156-02, respectively, are sold to a distributor.

6.1.2.3 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	P		000344156**	00050000		PP0233560	940690023	062397			0000000001	E25
PP1234567	S		00036415601	00000050		PM0105444	940690023	062397			0000000002	E25
PP1234567	S		00036415602	00000150		PM0105444	940690023	062397			0000000003	E25

6.1.2.4 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	P		000344156**	050000		PP0233560	940690023			70623	00001
PP1234567	S		00036415601	000050		PM0105444	940690023			70623	00002
PP1234567	S		00036415602	000150		PM0105444	940690023			70623	00003

6.1.3 Reporting Non-Manufacturing Activities

All non-manufacturing activities (i.e., those not described in Section 6 of this handbook) such

as acquisition transactions (i.e., codes P, R, G, V), disposition transactions (i.e., codes S, Y, T, Z,), inventory transactions (i.e., codes 1,3,5,8) and miscellaneous transactions (i.e., codes 7, F, X) will continue to be reported on the dates that the transaction actually occurred consistent with the format described in this handbook.

6.1.4 Manufacturing Reporting Guidelines

- Manufacturing activities (i.e., *transaction codes M, U, K, L, Q, J, W, and N*) may be reported quarterly or annually. In either instance the date of the manufacturing transaction activity must be shown as the last day of the calendar year or quarter being reported.

- When reporting specific manufacturing transaction codes identified in Section 6, the quantities of NDC products being reported may be expressed (a) by listing the amount of the NDC product containing the controlled substance in its original salt or derivative form (i.e., not converted to anhydrous base drug) or (b) in terms of anhydrous base controlled substance utilizing the salt conversion factors listed in Appendix 3. The ARCOS system will automatically convert all salt/derivative formulations to appropriate quantities of anhydrous controlled substance.

- If the manufacturer chooses to report in terms of anhydrous base substance, the NDC product being reported on the *transaction record* must reflect the anhydrous base substance and not the specific salt/derivative form.

- Please refer to the reporting matrix at Appendix 1 for automated reporting and at Appendix 2 for manual reporting as an aid in identifying the required fields of information for each acquisition, disposition, inventory, and manufacturing activity transaction code.

6.2 NARCOTICS

The specific types of ARCOS manufacturing activities required for all narcotics listed in Schedules I through III are:

a. **Quantity manufactured**.

This means the amount in grams of base weight of all reportable controlled substances manufactured or synthesized by the manufacturer. Base weight conversion factors are listed in Appendix 3.

b. **Quantity used for the manufacture of other preparations**.

This means the amount in grams of base weight of each controlled substance in

Schedules I and II used to produce (a) Schedule III, IV, or V preparations or (b) exempt chemical preparations (21 CFR 1308.23), or exempted prescription products (21 CFR 1308.32).

c. **Quantity held in stock on 31 December**.

This means the amount in grams of base weight of all reportable controlled substances that physically exists in the manufacturer's location as of December 31 of the reporting year. It is also essential that the manufacturer include that quantity of each controlled substance that is considered to be **in-process** material (i.e. that quantity of controlled substance which is not, at the time of the year-end inventory, in the bulk or finished dosage formulation stage). In-process inventory are those quantities of reportable drug stocks which are not included in a manufacturer's calculation of finished/dosage form inventory.

6.2.1 Manufacturing Narcotics

Code "M" is the *transaction code* to be used by all narcotic manufacturers that synthesize a controlled substance to produce the following: (a) bulk powder form, (b) large bulk quantities of formulated, but non-packaged tablets, capsules, or vials or large quantities (e.g., drum) of drugs in solution with known concentration. An "M" transaction is to be reported at the end of each calendar year or quarter and shall reflect the total quantity of each bulk substance produced during that reporting period. Individual "M" transactions for the same narcotic during the reporting period may be consolidated and reported as one "M" transaction.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "M" transaction. Note, also, that for each unique NDC number, *transaction code M* must be reported once at the end of each calendar quarter or annually on December 31.

For various reasons, if a quantity of controlled substance previously reported as manufactured must be returned to the production process (i.e. reworked), the only ARCOS data reported is the overall ***net change*** to the previously reported controlled substance.

a. If ***less*** is produced after reworking than was previously reported, an "N" transaction code (i.e. non-recovered waste) would be reported reflecting the ***difference*** in weight of controlled substance between the new manufactured data and the previously reported manufactured data. Do not report the newly manufactured product; report only the difference (i.e. code "N").

b. If ***more*** is produced after reworking than was previously reported, the

additional quantity of controlled substance in excess of the previously reported controlled substance is to be reported as an "M" transaction.

c. If no net change occurs with reworked material, nothing need be reported.

6.2.1.1 Manufacturing Scenario for "M" Transaction Code

On December 15, 1997, a manufacturer synthesized a total of 1,624,669 grams of thebaine (NDC 00406-1686-**), 100% pure.

6.2.1.2 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	M		004061686**	01624669	3			123197		1000	0000001234	E25

6.2.1.3 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	M		004061686**	001624	4				1000	71231	01234
PP1234567	M		004061686**	000669	3				1000	71231	01235

***NOTE**: Since the ARCOS Manual Report layout allows for only 6 positions in the quantity field, the manufacturer submits two transactions; one for the manufacture of 1,624 kilograms (unit=4) and the other for 669 grams (unit=3).*

6.2.2 Narcotics: Quantity Used To Produce Preparations

The "K" *transaction code* represents the mechanism used to identify the amount of narcotics used to produce Schedule III, IV, V, or exempt chemical preparations.

The "K" *transaction code **will*** be reported quarterly or annually on December 31 for each narcotic listed in Schedules I & II used to produce (1) Schedule III, IV & V preparations and/or (2) exempt chemical preparations (21 CFR 1308.23).

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "K" transaction. Note, also, that for each unique NDC number, *transaction code K* must be reported once at the end of each calendar quarter or annually on December 31.

6.2.2.1 Manufacturing Scenario for "K" Transaction Code

On April 30, 1997, a manufacturer utilized 10,134 milligrams of the bulk schedule II narcotic, hydrocodone bitartrate (NDC 00019-1582-**), 99% pure to produce a Schedule III, IV, V product or an exempt chemical preparation containing the same narcotic (i.e., hydrocodone

bitartrate).

6.2.2.2 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)       (4)             (5)       (6)  (7)  (8)     (9)     (10)  (11)        (12)         (13)
PP1234567   K       000191582**   00010134   2                  123197          0990     0000001000   E25
```

6.2.2.3 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)       (4)             (5)       (6)  (7)  (8)     (9)      (10)       (11-13)      (14)
PP1234567   K       000191582**    010134     2                           0990       61231      01000
```

6.2.3 Narcotics: Quantity Used to Produce a Different Narcotic

The United States is required to provide statistics reflecting the quantities of specific narcotics utilized to generate chemically different ARCOS reportable narcotic substances. *Transaction code U* is used to report this narcotic conversion data. The following list represents a few examples of the specific narcotics to be reported to the UN.

Substance Used	**Substance Obtained**
Opium	Morphine, Codeine, Thebaine
Codeine	Dihydrocodeine, Hydrocodone
Ecgonine	Cocaine
Thebaine	Codeine, Dihydrocodeine, Hydrocodone, Oxycodone, Thebacone, Buprenorphine, Nalbuphine, Naloxone, Naltrexone

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "U" transaction. Note, also, that for each unique NDC number, *transaction code U* must be reported once at the end of each calendar quarter or annually on December 31.

6.2.3.1 Manufacturing Scenario for "U" Transaction Code

On April 31, 1997, a manufacturer utilized 50kg of bulk codeine sulfate powder (NDC 00045-0974-**), 99% pure to produce 200 gm of dihydrocodeine, 98% purity. This scenario would require the submission of a "U" transaction to report the codeine sulfate utilization and a corresponding "M" transaction to report the manufacture of the narcotic substance which was produced (i.e., dihydrocodeine).

6.2.3.2 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers):

```
    (1)      (2) (3)       (4)             (5)       (6)  (7)  (8)     (9)     (10)  (11)        (12)         (13)
PP1234567   U       000450974**    00000050   4                  123197          0990     000000001    E25
```

```
PP1234567  M        000087803**     00000200     3              123197          0980    000000002    E25
```

6.2.3.3 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

```
   (1)     (2)  (3)      (4)            (5)         (6)   (7)   (8)      (9)      (10)     (11-13)      (14)
PP1234567  U        000450974**     000050       4                              0990     71231       00001
PP1234567  M       000087803**     000200       3                              0980     71231       00002
```

6.2.4 Inventory Held in Stock on 31 December

The “3" *transaction code* is used to report the annual year-end inventory of all ARCOS reportable controlled substances submitted by manufacturers and distributors in accordance with 21 CFR 1304.33. Inventories for all physically stored bulk or dosage form controlled substances are reported by a code “3" transaction. This inventory is to be taken at the close of business on December 31 of the reported year. ***THIS IS THE ONLY DATE WHICH WILL BE ACCEPTED FOR TRANSACTION CODE 3.***

Transaction code 4 is used to report the annual year-end in-process inventory for all reportable controlled substances by manufacturer in accordance with 21 CFR 1304.33. On December 31 of each year, certain manufacturers may have some quantities of controlled substances that are still in the manufacturing production chain (i.e., not a finished bulk or dosage form product). Manufacturing inventories of this type (i.e., in-process) are to be reported with a *transaction code 4*. The in-process manufacturing inventory is to be taken at the close of business on December 31 of the reported year. ***THIS IS THE ONLY DATE WHICH WILL BE ACCEPTED FOR TRANSACTION CODE 4.***

Please refer to Appendices 1 and 2 for additional information on the required fields of information for *transaction codes* “3“and “4“.

6.2.5 Manufacturing Scenarios for “3” and “4” Transaction Codes

On December 31, 1997, a manufacturer reported a year end inventory for (a) 53,967 grams of 100% pure bulk methadone hydrochloride (NDC 00019-1510-**), (b) 158,000 filled bottles of dronabinol capsules (NDC 00051-0021-01), (c) 89,000 ml of morphine sulfate solution (NDC 00054-3751-**) and (d) 365,000 liters of morphine sulfate solution (NDC 00186-0686-**) contained in the in-process production stream.

6.2.5.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

```
   (1)     (2)  (3)      (4)            (5)         (6)   (7)   (8)      (9)      (10)  (11)      (12)        (13)
PP1234567  3        000191510**     00053967     3              123197          1000  0000000001   E25
PP1234567  3        00051002101     00158000                    123197                0000000002   E25
PP1234567  3        000543751**     00089000     5              123197                0000000003   E25
PP1234567  4        001860686**     00365000     6              123197                0000000004   E25
```

6.2.5.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)        (4)              (5)      (6)    (7) (8)       (9)      (10)      (11-13)              (14)
PP1234567  3        000191510**      053967     3                          1000     71231     00001
PP1234567  3        00051002101      158000                                        71731               00002
PP1234567  3        000543751**      089000     5                                  71231               00003
PP1234567  4        001860686**      365000     6                                  71231               00004
```

6.3 PSYCHOTROPICS

The specific types of manufacturing activities required for all psychotropic substances listed in Schedules I through IV are:

a. **Quantity Manufactured**.

This means the amount of base weight controlled substance (in grams) manufactured or synthesized by the manufacturer. Base weight conversion factors are listed in Appendix 3.

b. **Quantity used for the manufacture of non-psychotropic substances**.

This means the quantity of bulk controlled substance used in a calendar quarter or year to produce a non-psychotropic substance. A non-psychotropic substance is any substance not listed in any Schedule of the 1971 Psychotropic Convention.

c. **Quantity used for the manufacture of exempt preparations**.

This means the quantity of bulk controlled substance used in a calendar quarter or year to produce (a) Excluded non-narcotic substances (21 CFR 1308.21), (b) Exempt chemical preparations (21 CFR 1308.23), or (c) Exempted prescription products (21 CFR 1308.31).

d. **Quantity held in stock on 31 December**.

This means the amount (in grams) of base weight of all reportable controlled substances that physically exists in the manufacturers' location as of December 31 of the reporting year. It is also essential that the manufacturer include that

quantity of each controlled substance that is considered to be in-process material (i.e., that quantity of controlled substance which is not, at the time of the time of the year-end inventory, in the bulk or finished dosage formulation stage).

6.3.1 Psychotropic Drugs

The psychotropic controlled substances for which manufacturing activities ***must*** be reported are as follows (shown by CSA Schedule and covered in 21 CFR 1304.33).
Manufacturers are not required to report acquisition or disposition transactions for any of the psychotropic controlled substances in Schedules III and IV listed below.

SCHEDULE I SUBSTANCES

(1) Diethyltryptamine
(2) Dimethyltryptamine
(3) Lysergic acid diethylamide(LSD, LSD-25)
(4) Mecloqualone
(5) Mescaline
(6) Psilocyn
(7) Psilocybin
(8) 4-methyl-2,5-dimethoxyamphetamine(STP)
(9) Tetrahydrocannabinols(THC, certain isomers)
(10)Ethylamine analogue of PCP(PCE)
(11)Pyrrolidine analogue of PCP(PCPy)
(12)Thiophene analogue of PCP(TCP)
(13)Methaqualone

SCHEDULE II SUBSTANCES

(1) Amobarbital
(2) Amphetamines
(3) Methamphetamine
(4) Secobarbital
(5) Methylphenidate
(6) Pentobarbital
(7) Phenmetrazine

(8) Phencyclidine (PCP)
(9) Glutethimide

SCHEDULE III SUBSTANCES

(1) Benzphetamine
(2) Cyclobarbital
(3) Methyprylon
(4) Phendimetrazine

SCHEDULE IV SUBSTANCES

(1) Barbital
(2) Diethylpropion (Amfepramone)
(3) Ethchlorvynol
(4) Ethinamate
(5) Lefetamine (SPA)
(6) Mazindol
(7) Meprobamate
(8) Methylphenobarbital
(9) Phenobarbital
(10)Phentermine
(11)Pipradrol

6.3.2 Manufacturing Psychotropics

Code “M” is the transaction code to be used by all psychotropic manufacturers actually synthesizing a controlled substance to produce (1) a bulk powder form, (2) large bulk quantities of formulated but ***non-packaged*** tablets, capsules, vials or (3) large quantities (e.g.,drum) of drugs in solution with known concentration. Those bulk manufacturers synthesizing a ***new*** chemical substance or producing a ***new*** chemical via an extraction process are to report this activity using an “M” *transaction code* designation.

An “M” transaction is to be reported each calendar quarter or year and shall reflect the total

quantity of each bulk chemical produced during the *reporting period*. Individual "M" transactions for the same psychotropic substance during the reporting period may be consolidated and reported as one "M" transaction.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "M" transaction. Note, also, that for each unique NDC number, *transaction code M* must be reported once at the end of each calendar quarter or annually on December 31.

6.3.2.1 Manufacturing Scenario for "M" Transaction Code

On June 30, 1997, a manufacturer synthesized a total of 4,669 grams of 3,4-methylenedioxyamphetamine (MDA) (NDC 00073-1002-**), 97% pure**.**

6.3.2.2 ARCOS Automated Report: (number in parenthesis indicate data field entries)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	M		000731002**	00004669	3			123197		0970	0000001234	E25

6.3.2.3 ARCOS Manual Report: (number in parenthesis indicate data field entries)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	M		000731002**	004669	3				0970	641231	01234

6.3.3 Psychotropics: Quantity Used to Make Non-Psychotropic Substances

The "U" transaction code is the mechanism employed to capture the conversion of the listed psychotropics to a non-psychotropic substance. The "U" transaction code will be used to report this activity on a quarterly or annual basis. Individual "U" transactions for the same psychotropic substances during the reporting period may be consolidated and reported as one "U" transaction.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "U" transaction. Note, also, that for each unique NDC number, *transaction code U* must be reported once at the end of each calendar quarter or annually on December 31.

6.3.3.1 Manufacturing Scenario for "U" Transaction Code

On September 30, 1997, a manufacturer purchased 75 kg of bulk levmethamphetamine base powder (NDC 00079-1470-**), 99% pure from another manufacturer under DEA order form number 942356780 and subsequently utilized 50 kg of bulk levmethamphetamine (NDC 00079-1470-**), to produce a non-psychotropic substance (i.e., selegiline). This scenario would require the submission of a "P" transaction to report the purchase of the bulk levmethamphetamine and a corresponding "U" transaction to report the levmethamphetamine utilization.

6.3.3.2 ARCOS Automated Report: (number in parenthesis indicate data field entries)

```
  (1)      (2) (3)     (4)           (5)     (6)    (7)          (8)        (9)  (10) (11)     (12)     (13)
PP1234567 P     000791470** 00000075  4  PG0208947  942356780 093097    0990  000001234  E25
PP1234567 U    000791470** 00000050  4                        123197     0970  000001235  E25
```

6.3.3.3 ARCOS Manual Report: (number in parenthesis indicate data field entries)

```
   (1)      (2) (3)      (4)          (5)    (6)      (7)          (8)      (9) (10)    (11-13)      (14)
PP1234567  P      000791470**  000075  4   PG0208947  942356780    0990      70930      01234
PP1234567  U      000791470**  000050  4                           0990          71231      01235
```

6.3.4 Psychotropics: Quantity Used to Manufacture Exempt Preparations

Transaction code K is used to report manufacturing activity involving the utilization of selected psychotropics to produce (1) exempt chemical preparations (21 CFR 1308.23), (2) excluded nonnarcotic substances (21 CFR 1308.21) or (3) exempted prescription products. (21 CFR 1308.32). The "K" *transaction code* will be used to report this activity on a quarterly or annual basis. Individual "K" transactions for the same psychotropic substances during the reporting period may be consolidated and reported as one "K" transaction.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "K" transaction. Note, also, that for each unique NDC number, *transaction code K* must be reported once at the end of each calendar quarter or annually on December 31.

6.3.4.1 Manufacturing Scenario for "K" Transaction Code

On March 31, 1997, a manufacturer utilized 4 milligrams of the bulk tenocyclidine hydrocloride powder (NDC 00079-0248-**), 99% pure to produce (a) an exempt chemical preparation containing the same psychotropic (i.e., tenocyclidine hydrochloride); (b) utilized 100 micrograms of bulk glutethimide powder (NDC 00079-0024-**) 98% pure to produce an exempted prescription product and utilized 250 grams of bulk meprobamate powder (NDC 00436-0809-**), 95% pure to produce an excluded substance.

6.3.4.2 ARCOS Automated Report: (TENOCYCLIDINE HCL) (numbers in parenthesis indicate data field entries).

```
   (1)      (2) (3)     (4)          (5)     (6)  (7)  (8)   (9)    (10)    (11)      (12)       (13)
PP1234567  K     000790248**  00000004   2         123197      0990    0000001234    E25
```

6.3.4.4 ARCOS Automated Report:
(GLUTETHIMIDE) (numbers in parenthesis indicate data field numbers)

```
     (1)      (2)  (3)     (4)          (5)    (6)    (7)     (8)    (9)       (10)     (11)        (12)         (13)
PP1234567   K       000790024**  00000100  1              123197            0980     0000001234     E25
```

6.3.4.5 ARCOS Manual Report: (GLUTETHIMIDE) (numbers in parenthesis indicate data

field numbers)

```
    (1)      (2) (3)      (4)            (5)      (6)   (7)   (8)     (9)       (10)     (11-13)        (14)
PP1234567   K       000790024**   000100   1                                  0980     71231         01234
```

6.3.4.6 ARCOS Automated Report: (MEPROBAMATE) (numbers in parenthesis indicate data field numbers)

```
    (1)      (2) (3)      (4)            (5)      (6)   (7)     (8)    (9)      (10)     (11)        (12)        (13)
PP1234567    K       0004360809**  00000250  3                123197          0950     0000001234    E25
```

6.3.4.7 ARCOS Manual Report: (MEPROBAMATE) (numbers in parenthesis indicate data field numbers)

```
    (1)        (2)    (3)      (4)              (5)      (6)  (7)     (8)     (9)      (10)     (11-13)        (14)
PP1234567     K          004360809**       000250    3                                 0950     71231         01234
```

6.3.5 Inventory Held in Stock on 31 December

Transaction code 3 is used to report annual year-end inventory of all ARCOS reportable controlled substances submitted by manufacturers and distributors in accordance with 21 CFR §1304.33. Inventories for all physically stored, bulk or dosage form controlled substances are reported by a code “3" transaction. This inventory is to be taken at the close of business on December 31 of the reporting year. ***THIS IS THE ONLY DATE WHICH WILL BE ACCEPTED FOR TRANSACTION CODE 3.***

Transaction code 4 is used to report the annual year-end ***in-process*** inventory for all reportable controlled substances by manufacturers in accordance with 21 CFR 1304.33. On December 31 of each year, certain manufacturers may have some quantities of controlled substances that are still in the manufacturing production chain (i.e., not a finished bulk or dosage form product). Manufacturing inventories of this type **(*i.e., in-process***) are to be reported with a *transaction code 4*. The ***in-process***

6.3.4.3 ARCOS Manual Report: (TENOCYCLIDINE HCL) (numbers in parenthesis indicate data field numbers)

```
 (1)       (2) (3)      (4)           (5)    (6)  (7) (8)    (9)     (10)  (11-13)      (14)
PP1234567   K       000790248**   000004  2                    0990   71231      01234
```

6.3.4.4 ARCOS Automated Report: (GLUTETHIMIDE) (numbers in parenthesis indicate data field numbers)

```
   (1)      (2) (3)     (4)            (5)     (6) (7)  (8)  (9)  (10)  (11)       (12)        (13)
PP1234567  K      000790024** 1  00000100 1          123197     0980     0000001234    E25
```

6.3.4.5 ARCOS Manual Report: (GLUTETHIMIDE) (numbers in parenthesis indicate data field numbers)

```
   (1)      (2) (3)      (4)           (5)     (6)  (7) (8)   (9)     (10)  (11-13)      (14)
PP1234567  K       000790024**    000100   1                   0980   71231      01234
```

6.3.4.6 ARCOS Automated Report: (MEPROBAMATE) (numbers in parenthesis indicate data field numbers)

```
   (1)      (2)  (3)      (4)           (5)     (6)  (7) (8)   (9)     (10)  (11)      (12)        (13)
PP1234567 K       004360809**  00000250  3           123197       0950  0000001234    E25
```

6.3.4.7 ARCOS Manual Report: (MEPROBAMATE) (numbers in parenthesis indicate data field numbers)

```
   (1)      (2) (3)      (4)           (5)    (6)  (7) (8)    (9)     (10)  (11-13)      (14)
PP1234567   K       004360809**    000250   3                   0950   71231      01234
```

6.3.5 Inventory Held in Stock on 31 December

Transaction code 3 is used to report annual year-end inventory of all ARCOS reportable controlled substances submitted by manufacturers and distributors in accordance with 21 CFR §1304.33. Inventories for all physically stored, bulk or dosage form controlled substances are reported by a code “3" transaction. This inventory is to be taken at the close of business on December 31 of the reporting year. ***THIS IS THE ONLY DATE WHICH WILL BE ACCEPTED FOR TRANSACTION CODE 3.***

Transaction code 4 is used to report the annual year-end ***in-process*** inventory for all reportable controlled substances by manufacturers in accordance with 21 CFR 1304.33. On December 31 of each year, certain manufacturers may have some quantities of controlled substances that are still in the manufacturing production chain (i.e., not a finished bulk or dosage form product). Manufacturing inventories of this type **(*i.e., in-process***) are to be reported with a *transaction code 4*. The ***in-process***

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "N" transaction. Note, also, that for each unique NDC number, *transaction code N* must be reported once at the end of each calendar quarter or annually on December 31.

Manufacturing Scenario for "N" Transaction Code

From February 1 through June 30, 1997, a manufacturer's journal on non-recoverable waste (CODE-N) was maintained and updated at the end of each day, reflecting a total of 250 grams of non-recoverable waste associated with the manufacture of bulk raw hydrocodone bitartrate powder (NDC 00373-4461-**) and a non-recoverable waste of 38 grams of bulk raw meprobamate powder (NDC 00074-5434-**).

6.4.1.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PG1234567	N		003734461**	00000250	3			123197		1000	0000000001	E25
PG1234567	N		000745344**	00000038	3			123197		1000	0000000002	E25

6.4.1.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PG1234567	N		003734461**	000250					1000	61231	00001
PG1234567	N		000745344**	000038	3				1000	61232	00002

6.4.2 Recovered Waste (Code W)

During the manufacturing processes of controlled narcotics and psychotropics, some bulk raw powder or bulk dosage form products may accumulate or be held in stock for later processing. A narcotic or psychotropic substance accumulated during the manufacturing process and held for later processing is recovered waste. In other instances, this residue cannot be reprocessed, but will be returned to storage (reported as recovered waste), accumulated for a period of time, and then destroyed. Any waste returned to inventory is considered recovered waste. Code "W" is the transaction code used to reflect this type of manufacturing activity. The "W" transaction activity must be reported quarterly or annually for each ARCOS reportable narcotic or psychotropic substance. Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "W" transaction. Note, also, that for each unique NDC number, *transaction code W* must be reported once at the end of each calendar quarter or annually on December 31.

Manufacturing Scenario for "W" Transaction Code:

From May 1 through August 30, 19977 a manufacturer's journal on recoverable waste (CODE-W) was maintained and updated at the end of each day, reflecting measurable losses of hydrocodone bitartrate capsules (NDC 00404-0016-**) and bulk phenobarbital raw powder (NDC 00019-6584-**) due to spillage, contamination, and/or machine residue accumulation. The following entries report the losses due to spillage (552 capsules) and machine residue accumulation (1250 GM raw powder).

6.4.2.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11	(12)	(13)
PG1234567	W		004040016**	00000552				123197			0000000001	E25
PG1234567	W		000196584**	00001250	3			123197	1000		0000000002	E25

6.4.2.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PG1234567	W		004040016**	000552						71231	00001
PG1234567	W		000196584**	001250	3				1000	71232	00002

6.4.3 Reversing (Code L)

Manufacturers involved in the normal production of preparations containing narcotic or psychotropic substances in Schedules III or IV, exempt chemical preparations, excluded products, or exempted prescription products may decide to recover the original bulk narcotic or psychotropic contained in the preparations for future use in other narcotic or psychotropic manufacturing procedures. Code "L" is the transaction code used to report this type of activity. The "L" transaction activity must be reported quarterly or annually for each ARCOS reportable narcotic or psychotropic substance recovered in schedules I and II. Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "L" transaction. Note, also, that for each unique NDC number, *transaction code L* must be reported once at the end of each calendar quarter or annually on December 31.

Manufacturing Scenario for "L" Transaction Code:

From May 1 through August 30, 1997, a manufacturer's journal on chemical procedures cited the chemical recovery of 30 kgs of bulk raw dihydrocodeine bitartrate powder (NDC 00794-0111-**) and 5260 grams of bulk raw butalbital powder (NDC

00441-0525-**) from exempt prescription products. The following examples demonstrate the ARCOS reporting procedure.

6.4.3.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

```
   (1)      (2) (3)      (4)            (5)     (6)  (7)  (8)     (9)     (10) (11)     (12)          (13)
PG1234567   L       007940111**  00000030  4                    123197  1000       0000000001       E25
PG1234567   L       004410525**  00005260  3                    123197  1000       0000000002       E25
```

6.4.3.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

```
   (1)      (2) (3)      (4)            (5)     (6)  (7)  (8)     (9)     (10)       (11-13)     (14)
PG1234567   L       007940111**  000030    4                    1000       71231      00001
PG1234567   L       004410525**  005260    3                    1000       71231      00002
```

6.4.4 Sampling (Code Q)

A quality control feature associated with most manufacturing procedures involves the removal of a designated quantity of the manufactured product for stability testing (i.e. melting point, flashpoint, optical rotation, GLC-NMR spectra, etc.) or government sampling requirements. Any quantity of ARCOS reportable bulk or dosage form narcotic or specific psychotropic product (see selected list, 6.3.1) removed from inventory for sampling purposes is to be reported. Code "Q" is the transaction code used to reflect this type of activity. The "Q" transaction activity must be reported quarterly or annually for each ARCOS Reportable narcotic or psychotropic substance in Schedules I through IV.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "Q" transaction. Note, also, that for each unique NDC number, *transaction code Q* must be reported once at the end of each calendar quarter or annually on December 31.

6.4.5 Return of Samples to Inventory (Code J)

There are occasions when samples removed for quality control are returned to the manufacturing process. Code "J" is the transaction code used to reflect this type of activity. For each unique NDC number, report one *transaction code J* for the reporting period.

Please refer to Appendices 1 and 2 for additional information on the required fields of information for the "J" transaction. Note, also, that for each unique NDC number, *transaction code J* must be reported once at the end of each calendar quarter or annually on December 31.

Manufacturing Scenarios for "Q" & "J" Transaction Codes:

The following example demonstrates the ARCOS reporting procedure for (a) removal of samples from inventory (Code Q) and (b) return of samples to inventory (Code J).

On May 22, 1997, a manufacturer withdrew a sample of 10 bottles of hydrocodone capsules

(NDC 00403-4522-30) for quality control testing; on November 10, 1997, the manufacturer returned 8 bottles of hyrdocodone bitartrate capsules (NDC 00403-4522-30) to inventory.

6.4.5.1 ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PG1234567	Q		00403452230	00000010				123197			00000001	E25
PG1234567	J		00403452230	00000008				123197			00000002	E25

6.4.5.2 ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PG1234567	Q		00403452230	000010						71231	00001
PG1234567	J		00403452230	000008						71231	00002

NOTE: <u>Exception to Usage Reporting</u>

There is one instance in manufacturing where no reporting is needed:

When a quantity of a drug is used to produce an end product (such as a preparation) which contains the same drug in the same schedule, no reporting is necessary. For example, if a Schedule II drug is used to produce a Schedule II preparation containing that drug, it is not reported to ARCOS.

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PART III: SYSTEM OUTPUT

SECTION 7 EDIT LISTINGS

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7

SECTION 7.0

EDIT LISTINGS

7.1 EDITING PROCESS

All ARCOS reports are initially subjected to two major procedures, the *control record* edit and the *transaction record* edit. These procedures check the reliability of the incoming data and determine whether and to what extent further processing will occur.

7.2 CONTROL RECORD EDIT

This initial procedure checks the *control record* submitted with each of the ARCOS reports. ARCOS reports that pass the validity tests performed on the *control record* continue on to the *transaction record* edit. An ARCOS report that fails the *control record* edit ***may*** be returned to the ARCOS registrant or central reporter for correction and resubmission. Returned reports are accompanied by a letter of explanation. Depending upon the nature and volume of the errors detected during the *control record* edit, the Data Systems Unit (ARCOS) may correct and resubmit a report ***after*** obtaining permission from the ARCOS registrant or central reporter.

7.3 TRANSACTION RECORD EDIT

The *transaction record* edit procedure examines all data fields in each incoming *transaction record* and rejects those records that do not meet pre-established criteria. This procedure produces the Daily Transaction Processing Error Report which is an error status report. The Daily Transaction Processing Error Report will either list all the *transaction records* with errors or contain a statement indicating that the current ARCOS report did not have any errors.

Receipt of the Daily Transaction Processing Error Report with no errors means that all the submitted *transaction records* were added to the ARCOS Master Transaction File. Exhibit 7.1: Accepted Report, illustrates the status report produced when no errors are detected.

When errors are detected, the Daily Transaction Processing Error Report lists each transaction record in error, the error code, a description of the error, and a correction number. These erroneous *transaction records* ***must*** be corrected and resubmitted with the next ARCOS report. Exhibit 7.2: Rejected Report, illustrates the report produced when *transaction records* fail the data reliability tests. Exhibits 7.1 and 7.2 are actual reports with the identifying data obliterated.

DATE: 03/01/97

DEPARTMENT OF JUSTICE

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DRUG ENFORCEMENT ADMINISTRATION
A R C O S 2
DAILY TRANSACTIONS PROCESSING

ERROR REPORT

Caldwell Incorporation
222 Squirrell Lane
Boston, IB 22344

ERRORS FOR CONTROL RECORD = = > PF9999999*033197M

THE ARCOS 2 TRANSACTION EDIT PROGRAM DID NOT FIND ANY ERRORS ON THE TRANSACTIONS SUBMITTED BY THE REPORTING REGISTRANT FOR THE CONTROL RECORD LISTED ABOVE.

Exhibit 7.1: Accepted Report

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DRUG ENFORCEMENT ADMINISTRATION
A R C O S 2
DAILY TRANSACTIONS PROCESSING
ERROR REPORT
Brown Incorporated
111 Howard Rd
Randolph, ST 11414

ERRORS FOR CONTROL RECORD = = > PB9999999*033197M

PB9999999 P 661570018600000000 3AB12345670307970000 2732 0000000010
E76 AN NDC NUMBER HAS BEEN ENTERED THAT COULD NOT BE FOUND IN THE DRUG FILE
E48 ASSOCIATE REGISTRANT NUMBER ENTERED ISN'T A VALID DEA REGISTRANT NUMBER
CORRECTION NUMBER: 00002732

PB9999999 P 661570017160000000 2CD12345670307970000 2731 0000000011
E76 AN NDC NUMBER HAS BEEN ENTERED THAT COULD NOT BE FOUND IN THE DRUG FILE
E48 ASSOCIATE REGISTRANT NUMBER ENTERED ISN'T A VALID DEA REGISTRANT NUMBER
CORRECTION NUMBER: 00002731

PB9999999 P 553014548670000013 2EF12345670306970000 2720 0000000012
E76 AN NDC NUMBER HAS BEEN ENTERED THAT COULD NOT BE FOUND IN THE DRUG FILE
CORRECTION NUMBER: 00002720

Exhibit 7.2: Rejected Report

7.4 TRANSACTION ERROR CODES

E01 Reporting Registrant Number Doesn't Match the One on the Control Record

Error Code E01 is issued when the Reporting Registrant's DEA registration number on the transaction record does not match the Reporting Registrant's DEA number on the control record.

E06 Delete Indicator Field Must Be Blank Or Must Be The Letters "A," "D," or "I"

The Action Indicator (formerly Delete Indicator) field must be blank or contain either an "A," "D," or "I." If it contains any other value, Error Code E06 is issued.

E07 Delete Indicator Field Must Be Blank If A Correction Number Is Present

Error Code E07 is issued when the Correction Number (formerly Lot Number) field is ***not*** blank and the Action Indicator (formerly Delete Indicator) field contains an "A," "D," or "I."

E12 Transaction Date Contains An Invalid Month And/Or An Invalid Day

Error Code E12 is issued when:

a. The Month is less than "01" or greater than "12"

b. The Day is less than "01" or greater than the maximum number of days in the month

c. The Year is not numeric

E13 Transaction Date Must Be The Last Day Of The Report Month Or Quarter

Error Code E13 refers to Transaction Code "7" ***only***. The Transaction Date field ***must*** be either the end of the month or the end of the quarter depending on the reporting frequency of the reporting registrant. Otherwise, Error Code E13 is issued.

E14 Transaction Code Requires A Year-End Date In The Transaction Date Field

Error Code E14 refers to inventory transaction codes “3,” “8,” and “4" ***only***. This error code is issued when the transaction date is not the last day of the year. The transaction date format is:

a. automated reporting: “1231**XX**” where “**XX**” is the year (last two-digits) in which the inventory was taken.

b. manual reporting: “**X**1231" where “**X**” is the year (last digit) in which the inventory was taken.

E15 Transaction Date Is Later Than The Run Date Of The ARCOS 2 Edit Program

The “run date” is the computer processing date. Error Code E15 is issued when the Transaction Date is the same or later than (i.e., in the future) the computer processing date. Transactions cannot be reported before they have occurred.

E16 Transaction Date Is Not Within The Reporting Registrants Report Period

Error Code E16 is issued when the Transaction Date is **before** or after the current reporting period ***and*** the transaction is ***not*** a correction, ***not*** a deletion, ***not*** an adjustment, ***and not*** a late transaction. The current reporting period is identified by the ending date and the reporting frequency (“M” or “Q”) entered on the control record.

E17 Transaction Date Isn’t Within The 2 Year Date Range Of The ARCOS System

The active ARCOS data base holds 24 months of data beginning with January 1, 1997. Transaction Records that have been in the active data base are archived after 24 months. Error Code E17 is issued when the transaction date is ***not*** within this range.

E21 Correction Number Entered Is Invalid. It Must Be Numeric

Error Code E21 is issued when the Error Correction Number field contains an invalid correction number or non-numeric data.

E22 Correction Number Is Not In The Error File

Error Code E22 is issued when the Error Correction Number on a Correction Transaction does ***not*** match a number in the Error file.

E25 The ARCOS Edit Still Found Errors On The Corrected Transaction

Error Code E25 is issued when a transaction flagged as a correction remains incorrect or contains a new error.

E28 Data Entered In The Quantity Field Is Invalid. It Must Be Numeric

Error Code E28 is issued when the Quantity field contains alphabetic or special characters. The Quantity field ***must only*** contain numeric data. This field is eight (8) digits in length for automated media and six (6) digits in length for manual media, including leading zeros. A zero quantity is invalid for all transaction codes, except for Transaction Code 5. The Quantity field is not checked for Transaction Codes F, 7, and 8.

E31 The Unit Value Entered Cannot Be Used With The Entered NDC Number

NDC identifies a finished dosage unit product:
Error Code E31 is issued when the Unit field is ***not*** blank, “D,” or “K.”

NDC identifies a raw bulk product (** package code):
Error Code E31 is issued when the Unit field is ***not*** a “1,”“2,” “3,” “4,” “5,” or “6.”

E32 Unit Value Must Be Blank, “D,” “K,” “1,” “2,” ”3,” “4,” “5,” or “6.”

Error Code E32 is issued when the Unit field is ***not*** blank, “D,” “K," ”1,” “2,” ”3,” “4,” “5”, or “6.”

E35 Strength Must Be Blank For Bulk Finished Or 0001 To 1000 For Bulk Raw

When the NDC identifies a ***finished bulk non-raw*** product:
The Strength field ***must*** be blank. Otherwise, Error Code E35 is issued.

When the NDC identifies a ***raw bulk*** product:
The Strength field ***must*** contain a value from "0001" to "1000". Otherwise, Error Code E35 is issued.

E36 Strength Is Invalid. Strength Must Be Blank Or Numeric

Error Code E36 is issued when the Strength field contains alphabetic or special characters. This field must be blank or contain a numeric value.

E40 Transaction Code Is Invalid. See The ARCOS Handbook For Valid Codes

The transaction code must be one of the following: "S," "P," "R," "Y," "T," "W," "M," "G," "Z," "N," "U," "V," "Q," "K," "J," "L," "X," "F," "1," "3," "4,, "5," "7,"or "8." Otherwise, Error Code E40 is issued.

E41 Transaction Code Is Reserved For Drug Manufacturers Only

Error Code E41 is issued when the reporting registrant is ***not*** a manufacturer, but reports a transaction using one of the following manufacturing transaction codes: "W," "M," "N," "U," "Q," "K," "J," "L," or "4."

E42 Transaction Code Requires Associate Registrant Number To Be Blank

Error Code E42 is issued when one of the following transaction codes is used: "T," "W," "M, "L," "N," "U," "Q," "J," "K," "F," "1," "3," "4," "5," "7," or "8" and the Associate Registration Number field (Field 7) is ***not*** blank.

E43 Associate Registrant Number Requires Transaction Code "Y," or "G," or "Z"

Error Code E43 is issued when the Associate Registrant Number field (Field 7) contains a DEA registration number for a DEA designated office or business and the transaction code is not Transaction Code Y, Transaction Code G, or Transaction Code Z.

E44 Transaction Code Conflicts With The NDC Number's CSA Schedule

Contact the Data Systems Unit (ARCOS) when Error Code 44 is issued. This error code applies to manufacturers ***only***. Certain drug schedules must be reported for certain manufacturing transaction codes.

E45 Transaction Code Requires An Associate Registrant Number Entry

Error Code E45 is issued when the transaction code is "S," "P," "R," "Y," "G," "Z," "V," or "X" ***and*** the Associate Registrant Number field (Field 7) does ***not*** contain a valid DEA registration number or one of the following entries, left justified: "RECALL," "OFFICER," "CIVILDEF," "UNKNOWN," "VESSELS," "NATIVE," or "MILITARY."

E46 Associate Registrant Number Is Invalid For Transaction Code "Y/G/Z"

Error Code E46 is issued when:

a. the firm holding the DEA registration number entered in the Associate Registrant Number field (Field 7) is ***not*** authorized to handle a ***Transaction Code Y*** activity (destruction of controlled substances) ***or***

b. the firm holding the DEA registration number entered in the Associate Registrant Number field (Field 7) is ***not*** authorized to handle a ***Transaction Code G or Z*** activity (controlled substances supplied or received by government).

E47 Associate Registrant Number Can't Equal Reporting Registrant Number

Error Code E47 is issued when the Associate Registrant Number (Field 7) is the same as the Reporting Registrant Number (Field 1). These two fields ***must not*** contain the same data.

E48 Associate Registrant Number Is Not A Valid DEA Registrant Number

Error Code E48 is issued when the DEA registration number entered in the Associate Registrant Number field (Field 7) is ***not*** found on DEA's master list of valid registration numbers.

E49 Associate Registrant Number Is Invalid For The Transaction Code

Error Code E49 is issued when the Associate Registrant Number field (Field 7) contains the entry “CIVILDEF,” “RECALL,” “OFFICER,” “UNKNOWN, ”VESSELS,” “NATIVES,” OR “MILITARY” and the corresponding transaction code entered in the Transaction Code field (Field 2) is incorrect. The correct pairing for the Associate Registrant Number field (Field 7) and the Transaction Code field is:

“CIVILDEF”	use	Transaction Codes	“S,” “P,” or “G”
“OFFICER”	use	Transaction Codes	“S,” “P,” “G,” or “Z”
“RECALL”	use	Transaction Codes	“S” or “P”
“UNKNOWN”	use	Transaction Code	“V”
“VESSELS”	use	Transaction Codes	“S” or “P”
“NATIVE”	use	Transaction Codes	“S” or “P”
“MILITARY”	use	Transaction Codes	“S” or “P”

E52 The Order Form Number Has Not Been Correctly Entered

Error Code E52 is issued when an invalid Order Form Number has been entered in the DEA Order Form Number field (Field 8).

E53 The Order Form Number Is Required For Schedule 1 & 2 Drugs

Error Code E53 is issued when the Transaction Code is “S,” “P,” “R,” “V,” or “X”, the NDC identified the product as a Schedule I or II controlled substance, ***and*** the Order Form Number field (Field 8) is blank.

E60 Transaction Code 1 -- An Inventory Record Already Exists

Error Code E60 is issued when a Schedule Change Inventory transaction record for the same NDC product already exists on the Master Transaction File.

E61 Transaction Code 3 or 8 -- Year-End Inventory Amount Already Exists

Error Code E61 is issued when:

a. A code 3 transaction record ***for the same NDC product*** has previously been added to the Master Transaction File or

b. A code 8 transaction record has previously been added to the Master Transaction File.

Delete the previously submitted transaction code 3 or transaction code 8 before resubmitting a different year end inventory amount.

E75 The NDC Number Is Invalid, It Contains One Or More Spaces

Error Code E75 is issued when the NDC is not in the format required by ARCOS or no NDC has been entered.

E76 The NDC Number Is Not In The Drug File

Error Code E76 is issued when the NDC can't be found in the ARCOS Master Drug file. To add a product to the ARCOS Master Drug File, manufactures, repackers, and relabelers must provide the Data Systems Unit (ARCOS) with the product's label, a copy of the label, or the completed FDA Drug Product Listing form (FDA-2657).

E77 NDC Number Isn't ARCOS Reportable. Don't Submit Corrected Transaction

Error Code E77 is issued when the product described by the NDC is ***not*** reportable to ARCOS. Do ***not*** re-submit any transactions for this product.

7.5 CORRECTING TRANSACTION RECORDS

Error processing for both ARCOS registrants and DEA has been simplified and streamlined. For registrants submitting ARCOS reports on magnetic media (automated), corrections, deletions, adjustments, and late transactions can be submitted ***along with*** the next monthly or quarterly report. There is no longer any need for errata media. Transactions for corrections, deletions, adjustments, and late items are placed ***after*** the last transaction in the current report. See Section 4, Control Record, for examples.

ARCOS registrants reporting on manual media (DEA Form 333), also submit corrections, deletions, adjustments, or late transactions ***along with*** the next monthly or quarterly report. As with reporting on magnetic media, reporters using the DEA Form 333 must keep the *control record* and its associated transactions together. Corrections, deletions, adjustments, and late transactions are coded on the DEA Form 333 ***after*** the last transaction of the current report. See Section 4, Control Record, for examples.

7.5.1 Error Categories

The following four types of transactions are used to correct errors and omissions in previously submitted ARCOS:

- **Correction Transaction**

  A Correction Transaction ***corrects*** a *transaction record* that has been rejected by the ARCOS editing programs. This transaction is submitted ***only after*** the original transaction has been listed on the Daily Transaction Processing Error Report as a rejected transaction..

- **Delete Transaction**

  The Delete Transaction ***removes*** a *transaction record* from the Master Transaction File. A Delete Transaction is submitted when the existing *transaction record* will ***not*** be replaced.

- **Adjustment Transaction**

  An Adjustment Transaction is used when the ARCOS editing programs have not rejected an original transaction, but the transaction is found by the submitting registrant to be inaccurate. In these instances, the Daily Transaction Processing Error Report will not list the *transaction record*. The Adjustment Transaction replaces the originally inaccurate *transaction record* in the Master Transaction File.

- **Late Transaction**

  A *transaction record* that was ***omitted*** from a ***prior*** report is ***submitted*** with the ***current*** report using the Late Transaction.

7.6 CORRECTION TRANSACTION

A Correction Transaction ***corrects*** a transaction that has been rejected by the data validation procedures. Rejected *transaction records* are listed in the Daily Transaction Processing Error Report and have been added to the *ARCOS transaction error file*.

7.6.1 Error Report

The Daily Transaction Processing Error Report will be mailed to each reporter after the transactions have been through the data validation procedures. The error report includes the following information:

a. Each transaction that contains one or more errors.

b. An error code and its meaning for each error.

c. A *correction number* for each erroneous transaction.

The *Correction Number* can be found on the error report, listed ***under*** the errors for each transaction and labeled "Correction No." Exhibit 7.3: Sample Error Transactions are transactions as they appear on the error report. However, for these examples, the ***errors*** and the ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol.

ERRONEOUS TRANSACTIONS

PA9999999S 0054375144000000002 **B9**9900099**PO**2463899070694 0000000102E25
^^ ^^

E48 ASSOCIATE REGISTRANT NUMBER IS INVALID OR RETIRED MORE THAN 2 YEARS AGO

E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED ON THE TRANSACTION

CORRECTION NO. **00000022**
^^^^^^^^

PA9999999S 0054375144000000002 B99900099**P0**2463899**13**0694 0000000102E25
^^ ^^

E12 THE TRANSACTION DATE CONTAINS EITHER AN INVALID MONTH OR AN INVALID DAY

E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED ON THE TRANSACTION

CORRECTION NO. **00000023**
^^^^^^^^

Exhibit 7.3: Sample Error Transactions

7.6.2 Correction Process

A Correction Transaction ***must be*** submitted for each erroneous transaction to be corrected. To correct a rejected record, submit a correction transaction with the ***next quarterly*** or ***monthly*** report. Correction Transactions ***may be placed after*** the transactions for the current reporting period. See Exhibit 4.2: Record Placement for ARCOS Report and Exhibit 4.3: ARCOS Registrant's Report.

7.6.3 Correction Record

The *correction transaction record* has two formats, one for automated reporting and one for manual reporting. They are the ***same*** formats as the ARCOS *transaction record* formats with one exception - - the addition of the *correction number*. The *correction transaction record* ***must*** contain:

a. ***all*** the fields that were correct on the original submission ***including*** the original transaction identifier

b. the corrected fields

c. the *correction number*

7.6.4 Correction Number

A *correction number* is assigned to each erroneous transaction during the data validation process. This number is a unique, 8-digit, sequential number. There is ***only one*** *correction number* per erroneous transaction, even when a transaction has multiple errors.

7.6.4.1 Correction Number Format

The format for the *correction number* is: NNNNNNNN. Examples of this unique, sequential number are: 00000422, 00000423, and 00000424.

7.6.4.2 Correction Number Position

The *correction number* occupies the space formerly identified as the “Lot Number” field on the *transaction record*, Field 10 (automated media) and Field 9 (Manual Media, DEA Form 333). The field positions are:

a. positions 56 - 63 (automated media)

or

b. positions 48 - 55 (manual media, DEA Form 333)

7.6.5 Correction Transaction Examples

7.6.5.1 Automated Media

The following transaction would appear on the error report sent from DEA (ARCOS). *For this example*, the ***errors*** and ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999S 0054375144500000002 **B9**9900099**PB**2463899070697 0000000102E25
^^ ^^

E48 ASSOCIATE REGISTRANT NUMBER IS INVALID OR RETIRED MORE THAN 2 YEARS AGO

E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED ON THE TRANSACTION

CORRECTION NO. **00000422**
^^^^^^^^

These errors ***must*** be corrected by including the following correction transaction in the ***next*** monthly or quarterly ARCOS report. *For this example*, the ***corrections*** and ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999S 0054375144500000002 **BB**9900099**PB**2463899070697**00000422** 0000000102E25
^^ ^^ ^^^^^^^^

7.6.5.2 Manual Media

The following transaction would appear on the error report sent from DEA (ARCOS). *For this example*, the ***errors*** and ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol. underneath with the "^" symbol.

PA9999999S 00543751444000002 **AB**9900099**PB**2463899 7022800102
^^ ^^

E48 ASSOCIATE REGISTRANT NUMBER IS INVALID OR RETIRED MORE THAN 2 YEARS AGO

E52 THE ORDER FORM NUMBER HAS NOT BEEN CORRECTLY ENTERED ON THE TRANSACTION

CORRECTION NO. **00000422**
^^^^^^^^

These errors ***must*** be corrected by including the following correction transaction in the ***next*** monthly or quarterly ARCOS report. For this example, the ***errors*** and ***correction number*** are in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999S 00543751444000002 **AA**9900099**PB**2463899**00000422** 7022800102
^^ ^^ ^^^^^^^^

7.7 DELETION TRANSACTION

7.7.1 Delete Process

The Deletion Transaction ***removes*** a *transaction record* from the Master Transaction File. A *deletion record* is submitted when the ***existing*** *transaction record* will ***not*** be replaced. To remove an existing record from the Master Transaction File submit a *deletion record* with the ***next*** monthly or quarterly report. *Deletion records* ***may be placed after*** the *transaction records* for the current reporting period. See Exhibit 4.2: Record Placement for ARCOS Report and Exhibit 4.3: ARCOS Registrant's.

7.7.2 Deletion Record

The *deletion record* is a ***duplicate*** of the original *transaction record* plus the *delete indicator*. The *deletion record* ***must*** contain:

a. ***all*** the fields that were in the original *transaction record*, ***including*** the original *transaction identifier* number.

b. "D" in the *action indicator* (formerly *delete indicator*) field, position 11 (Field 3).

7.7.3 Deletion Examples

An ARCOS registrant wants to remove the following *transaction record* from the data base. Examples of both automated and manual reporting are provided. The *action indicator* "D" (delete), appears in **bold-faced** type and marked underneath with the "**^**" symbol.

Original Transaction Record: automated media

PA9999999S 0054375144700000008 AB990009940246389907039 7 0000000102E25

Deletion Record: automated media

PA9999999S **D**0054375144700000008 AB990009940246389907039 7 0000000102E25
^

Original Transaction Record: manual media

PA9999999S 00543751444000002 AB9900099PB2463899 7022800102

Deletion Record: manual media

PA9999999S **D**00543751444000002 AB9900099PB2463899 7022800102
^

7.8 ADJUSTMENT TRANSACTION

DEA (ARCOS) recognizes two types of *transaction record* flaws in ARCOS data: mistakes and errors. Errors are data flaws caught by the ARCOS programs during the data validation process. *Transaction record*s containing errors are added to the Error Transaction File. These records must be corrected and resubmitted.

Mistakes are data flaws ***not*** caught by the ARCOS programs but discovered by the submitting ARCOS registrant. *Transaction records* containing mistakes ***are added*** to the Master Transaction File, since these records have met all the processing criteria. For example, the submitting ARCOS registrant enters "20" in the *quantity* field. This entry passes the data validity tests and the *transaction record* is added to the data base. However, the reporting registrant had originally ***intended*** to enter "200", but had mistakenly entered "20 ". That mistake would ***not*** be caught by the data validity tests. This *transaction record* with the ***incorrect, but valid*** data would be added to the Master Transaction File. This mistake must be ***rectified*** by using the adjustment transaction. An adjustment transaction ***revises*** a *transaction record* that has been added to the Master Transaction File.

7.8.1 Adjustment Process

The Adjustment Transaction corrects an existing ARCOS Master Transaction File record by replacing it. When an ARCOS registrant discovers a mistake in a previously submitted

transaction, the registrant ***must wait until*** the Daily Transaction Processing Error Report is

received from DEA (ARCOS) ***before*** taking any action. Whether or not the transaction is listed in the error report determines whether an Adjustment Transaction or a Correction Transaction must be submitted.

A transaction containing mistakes that can ***only*** be identified by the ARCOS registrant is ***not*** listed in the Error Report. In this case an ***Adjustment Transaction must*** be submitted to correct the mistake. A transaction containing ***both errors and mistakes*** is rejected and listed in the error report. However, only the errors are specifically identified and listed in the error report. Mistakes ***are not*** caught by the ARCOS programs, and therefore, are not specifically listed in the error report. A ***Correction Transaction must*** be used to correct this *transaction record*. See Section 7.6, Correction Transaction. Both the Adjustment Transaction or Correction Transaction ***must*** be submitted with the ***next*** monthly or quarterly ARCOS report ***after*** the error or mistake has been discovered. These transactions ***may be placed after*** the transactions for the current reporting period. See Exhibit 4.2: Record Placement for ARCOS Report and Exhibit 4.3: ARCOS Registrant's Report.

7.8.2 Adjustment Records

An Adjustment Transaction consists of ***two*** records, the *deletion record* and the *adjustment record*

7.8.2.1 Deletion Record

The *deletion record* is the ***first*** record of the two records. It is a ***duplicate*** of the original *transaction record* plus the *action indicator*. The *deletion record* ***must*** contain:

a. ***all*** the fields that were in the original *transaction record*, ***including*** the original *transaction identifier* number.

b. "D" in the *action indicator* (formerly *delete indicator*) field, position 11 (Field 3).

7.8.2.2 Adjustment Record

The ***second*** record of the two records, the *adjustment record*, is the ***revised*** *transaction record*. The *adjustment record* ***must*** contain:

a. ***all*** the fields that ***were correct*** in the original transaction ***including*** the original *transaction identifier* number.

b. ***all*** the ***corrected*** fields.

c. "A" in the *action indicator* (formerly *delete indicator*) field, position 11 (Field 3).

7.8.3 Adjustment Transaction Examples

7.8.3.1 Automated Media: Incorrect Quantity

In the original transaction the *quantity* field was mistakenly coded as "00000002." However, since this quantity met the editing criteria, the transaction was accepted and added to the Master Transaction File. This *transaction record* ***does not*** appear on the error report, but the original entry was incorrect and must be changed to the correct amount, "00000020"(i.e., from "2" to "20").

Original Transaction

The following transaction, originally reported to DEA (ARCOS), ***does not*** appear on the Daily Transaction Processing Error Report. This indicates that the Adjustment Transaction, rather than the Correction Transaction, ***must*** be submitted to correct the mistake. *For this example*, the incorrect *quantity* field appears in **bold-faced** type and underneath with the "^" symbol.

PA9999999S 0054375144000000**02** AB990009940246389907039 4 0000000102E25
^^

Adjustment Pair

The following adjustment pair was submitted to correct the *quantity* field. *For this example,* the *quantity* field and the *action indicator* (formerly *delete indicator*) field appear in **bold-faced** type and marked underneath with the "^" symbol.

Deletion Record

PA9999999S**D**0054375144000000**02** AB990009940246389907039 4 0000000102E25
^ ^^

Adjustment Record

PA9999999S**A**0054375144000000**20** AB990009940246389907039 4 0000000102E25
^ ^^

7.8.3.2 Automated Media: Wrong Transaction Code

This next adjustment example changes an incorrect *transaction code*. A "sales" *transaction record* was mistakenly submitted. Originally, the *transaction record* should have been submitted as a "purchase" transaction.

Original Transaction

The following transaction, originally reported to ARCOS, does ***not*** appear in the Daily Transaction Processing Error Report. This indicates that the Adjustment Transaction, rather than the Correction Transaction, ***must*** be submitted to correct the mistake. *For this example*, the incorrect *transaction code* field is in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999**S** 0054375144000000012 AB990009940246389907199 4 0000000199E25
^

Adjustment Pair

The following adjustment pair was submitted to correct the mistake in the *transaction code* field. *For this example*, the *transaction code* field and the *action indicator (*formerly *Delete Indicator)* field are in **bold-faced** type and marked underneath with the "**^**" symbol.

Deletion Record

PA9999999**SD**0054375144000000012 AB990009940246389907199 4 0000000199E25
^^

Adjustment Record

PA9999999**PA**0054375144000000012 AB990009940246389907199 4 0000000199E25
^^

7.8.3.3 Manual Media: Incorrect Quantity

In the original transaction the *quantity* field was mistakenly coded as “000005.” Nevertheless, this quantity met the editing criteria, the *transaction record* was accepted, and added to the data base. This transaction ***does not*** appear on the error report, but since the original entry was incorrect, it ***must*** be changed to the correct amount “000050“ (i.e., from “5“ to “50“).

Original Transaction

The following transaction, originally reported to ARCOS, ***does not*** appear on the Daily Transaction Processing Error Report. This indicates that the Adjustment Transaction, rather than the Correction Transaction, ***must*** be submitted to correct the mistake. *For this example*, the incorrect *quantity* field is in **bold-faced** type and marked underneath with the “**^**” symbol.

PA9999999S 00543751440000**05** AB9900099402463899 4070300102
^^

Adjustment Pair

The following adjustment pair was submitted to correct the *quantity* field. *For this example,* the *action indicator* (formerly *Delete Indicator)* field and the *quantity* field are in **bold-faced** type and marked underneath with the “^” symbol.

Deletion Record

PA9999999S**D**00543751440000**05** AB9900099402463899 4070300102
^ ^^

Adjustment Record

PA9999999S**A**00543751440000**50** AB9900099402463899 4070300102
^ ^^

7.8.3.4 Manual Media: Wrong Transaction Code

The next adjustment example changes an incorrect *transaction code*. A "sales" *transaction record* was mistakenly submitted. Originally, the *transaction record* should have been submitted as a "purchase" transaction.

Original Transaction

The following transaction, originally reported to DEA (ARCOS), ***does not*** appear on the Daily Transaction Processing Error Report. This indicates that the Adjustment Transaction, rather than the Correction Transaction, ***must*** be submitted to correct the mistake. *For this example*, the incorrect *transaction code* is in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999**S** 00543751440000012 AB9900099402463899 4071900199
^

Adjustment Pair

The following adjustment pair was submitted to correct the *transaction code* field. For this example, the *transaction code* field and the *action indicator* (formerly *Delete Indicator)* field are in **bold-faced** type and marked underneath with the "^" symbol.

Deletion Record
PA9999999**SD**00543751440000012 AB9900099402463899 4071900199
^^
Adjustment Record
PA9999999**PA**00543751440000012 AB9900099402463899 4071900199
^^

7.9 LATE TRANSACTION

The Late Transaction enables a *transaction record* omitted from a prior ARCOS report to be accepted with the current ARCOS report.

7.9.1 Reporting Period and Frequency

ARCOS registrants must report their controlled substance transactions to DEA (ARCOS) on a monthly or a quarterly basis. Each ARCOS report, ***except*** for transactions that adjust, delete, or correct previously submitted transactions, ***must only*** contain controlled substance transactions that are within the period being reported. A monthly reporter with a reporting period ending date of February 28, 1997 (022897) on the *control record*, must have *transaction records* with dates that are from February 1, 1997 through February 28, 1997 (except for corrections, deletions, adjustments, and late transactions). A quarterly reporter with a reporting period ending date of June 30, 1997 (063097) on the *control record*, must have *transaction records* with dates that are from April 1, 1997 through June 30, 1997 (except for corrections, deletions, adjustments, and late transactions).

7.9.2 Reporting Period Test

ARCOS processing checks the *transaction date* of each *transaction record* to determine if it is within the ARCOS registrant's current reporting period. Each transaction that falls outside of the current reporting period ***and*** is ***not*** identified as a late, correction, adjustment, or deletion transaction is rejected as erroneous. These transactions appear on the Daily Transaction Processing Error Report with an error message indicating that the *transaction date* is not within the current reporting period.

Example 1:

An ARCOS registrant with a monthly reporting frequency includes *transaction records* with February *transaction dates* in its March ARCOS report. These *transaction records* are neither adjustments nor corrections to previously submitted transactions; they are being reported for the first time. Since the *transaction dates* reported lie outside the current reporting period, March, the *transaction records* are rejected and listed on the Daily Transaction Processing Error Report.

Example 2:

An ARCOS registrant with a quarterly reporting frequency includes *transaction records* with second quarter (April, May, June) *transaction dates* in its third quarter (July, August, September) ARCOS report. These *transaction records* are neither adjustments nor corrections to previously submitted transactions; they are being reported for the first time. Since the *transaction dates* reported lie outside the current reporting period, the third quarter of the year, the *transaction records* are rejected and listed on the Daily Transaction Processing Error Report.

7.9.3 Submission and Acceptance

A Late Transaction is submitted as an Insertion Record. This record has an "***I***" coded in the *action indicator* (formerly *Delete Indicator*) field (Field 3). A Late Transaction that is missing the insertion code, "I," in the *action indicator* field, will be rejected with an E16, *transaction date* Is Not Within the Reporting Registrants Report Period" error code. ***Late Transactions*** are included in an ARCOS Registrant's current report. They may be placed ***after*** the transactions for the current reporting period. See Exhibit 4.2: Record Placement for ARCOS Report and Exhibit 4.3: ARCOS Registrant's Report.

7.9.4 Late Transaction Examples

7.9.4.1 Automated Media: Late Transaction

A January transaction was inadvertently omitted from a monthly reporter's January 1997 report. Subsequently, the transaction was submitted in the reporter's March 1997 report. To have this transaction pass the pass the *transaction date* test, an "***I***" ***must*** be entered in the *action indicator* (formerly *Delete Indicator*) field (Field 3, position 11). The transaction below illustrates the correct coding when a late transaction is ***initially*** submitted. For this example, the *transaction date* field and the *action indicator (*formerly *Delete Indicator)* field are in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999S**I**00543751440000000 20 AB990009940246389**9010697** 0000000102E25
^ ^^^^^^

7.9.4.2 Manual Media: Late Transaction

An April transaction was inadvertently omitted from a monthly reporter's April 1997 report. Subsequently, the transaction was submitted in the reporter's July 1997 report. To have this transaction pass the pass the *transaction date* test, an ***"I" must*** be entered in the *action indicator* (formerly *delete indicator*) field (Field 3, position 11). The transaction below illustrates the correct coding when a late transaction is ***initially*** submitted. For this example, the *transaction date* field and the *action indicator (*formerly *delete indicator)* field are in **bold-faced** type and marked underneath with the "^" symbol.

PA9999999S**I**00543751440000020 AB9900099402463899 **70406**00102
^ ^^^^^

7.9.5 TRANSACTION IDENTIFIER

The *transaction identifier* for a late transaction is the next, sequential number in the ARCOS report for the reporting period in which the late transaction should have occurred. For example, an ARCOS registrant is submitting three late transactions with its current quarterly report for the quarter ending June 30, 1997. One late *transaction record* has a *transaction date* occurring in January, and the other two have *transaction dates* occurring in March. These three transactions were omitted from the ARCOS report for the first quarter of 1997. The *transaction identifiers* for these three late transactions will be the next three sequential numbers that ***would have occurred*** in the ARCOS report for the first quarter of 1997.

APPENDIX 1

ARCOS TRANSACTION MATRIX: AUTOMATED REPORTS

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Trans. Date (9)	Correct. Number (10)	Strength (11)	Trans. Identif. (12)	Doc. Identif. (13)
INVENTORY TRANSACTIONS													
Sched. Chng.	B	1		B	B	O			B	O	O	B	B
Year-end	B	3		B	B	O			B	O	O	B	B
In-Process	B	4		B	B	O			B	O	O	B	B
Special	B	5		B	B	O			B	O	O	B	B
No Year-end	B	8							B	O		B	B
ACQUISITION TRANSACTIONS													
Purchase or Other Receipt	B	P		B	B	O	ASSOC REG # OR RECALL B, C	H	B	O	O	B	B
Return	B	R		B	B	O	ORIG. ASSOC REGIS. # B, C	ORIG. DEA ORD. FORM H	B	O	O	B	B
Recovered Waste	B	W		B	B	O			B	O	O	B	B
Manufactured	B	M		B	B	O			B	O	O	B	B
Reversing	B	L		B	B	O			B	O	O	B	B

B Mandatory.
C Normally: Associate Registrant Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSELS, NATIVE, & MILITARY
* Normally: Associate Registrant Number or UNKNOWN
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Trans. Date (9)	Correct. Number (10)	Strength (11)	Trans. Identif. (12)	Doc. Identif. (13)
Government Supplied	B	G		B	B	O	DEA/FDA #, OFFICER, OR CIVIL DEF B		B	O	O	B	B
Ret. Sample to Inventory	B	J		B	B	O			B	O	O	B	B
Unsol. Return	B	V		B	B	O	B, *	H	B	O	O	B	B
DISPOSITION TRANSACTIONS													
Sale, Disposition, or Transfer	B	S		B	B	O	ASSOC REGIS #, RECALL B, C	H	B	O	O	B	B
Destroyed	B	Y		B	B	O	DEA REGIONAL # B		B	O	O	B	B
Theft	B	T		B	B	O			B	O	O	B	B
Non-recov. Waste	B	N		B	B	O			B	O	O	B	B
Used in Prod.	B	U		B	B	O			B	O	O	B	B
Used in Prep.	B	K		B	B	O			B	O	O	B	B

B Mandatory.
C Normally: Associate Registration Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSEL, NATIVE, MILITARY
* Normally: Associate Registrant Number or UNKNOWN
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Trans. Date (9)	Correct. Number (10)	Strength (11)	Trans. Identif. (12)	Doc. Identif. (13)
Receipt by Government or Seizure	B	Z		B	B	O	DEA/FDA #, OFFICER B		B	O	O	B	B
Sampling	B	Q		B	B	O			B	O	O	B	B
DELETION, ADJUSTMENT, AND LATE TRANSACTIONS													
Deletion	B	B	D	Fields 2 and 4-13: Enter the same information as was entered on the original transaction.									
Adjustment	B	B	A	Fields 4-13: Enter the original information for unchanged fields and the revised information for changed fields.									
Late	B	B	I	Fields 4-13: Enter normal transaction information.									
MISCELLANEOUS TRANSACTIONS													
No Period Act	B	7							B			B	B
Lost-in-Transit	B	X		B	B	O	B	H	B		O	B	B
Order DEA Form 333	B	F			O				B			B	B

B Mandatory.
C Normally: Associate Registrant Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSELS, NATIVE, & MILITARY
* Normally: Associate Registrant Number or UNKNOWN
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

APPENDIX 2
ARCOS TRANSACTION MATRIX: MANUAL REPORTS

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Correction Number (9)	Strength (10)	Trans. Date, Yr (11)	Trans. Date, Mo (12)	Trans. Date,Day (13)	Trans. ID (14)
INVENTORY TRANSACTIONS														
Sch. Chg	**B**	**1**		**B**	**B**	**O**			**O**	**O**	**B**	**B**	**B**	**B**
Year-end	**B**	**3**		**B**	**B**	**O**			**O**	**O**	**B**	**B**	**B**	**B**
In-Proc	**B**	**4**		**B**	**B**	**O**			**O**	**O**	**B**	**B**	**B**	**B**
Special	**B**	**5**		**B**	**B**	**O**			**O**	**O**	**B**	**B**	**B**	**B**
No Yr end	**B**	**8**							**O**		**B**	**B**	**B**	**B**
ACQUISITION TRANSACTIONS														
Purchase or Other Receipt	**B**	**P**		**B**	**B**	**O**	ASSOC REG # OR RECALL B, C	H	O	O	B	B	B	B
Return	B	R		B	B	O	ORIGINAL ASSOC REG NUMBER B, C	ORIGINAL ORDER FORM NUMBER H	O	O	B	B	B	B
Recov. Waste	B	W		B	B	O			O	O	B	B	B	B
Manufac.	B	M		B	B	O			O	O	B	B	B	B
Reversing	B	L		B	B	O			O	O	B	B	B	B

B Mandatory.
C Normally: Associate Registrant Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSELS, NATIVE, & MILITARY
* Normally: Associate Registrant Number or UNKNOWN.
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Correction Number (9)	Strength (10)	Trans. Date, Yr (11)	Trans. Date, Mo (12)	Trans. Date,Day (13)	Tranced (14)
Govern-ment Supplied	B	G		B	B	O	DEA/FDA # OFFICER CIVILDEF B		O	O	B	B	B	B
Return Sample to Inventory	B	J		B	B	O			O	O	B	B	B	B
Unsol. Return	B	V		B	B	O	B, *	H	O	O	B	B	B	B
DISPOSITION TRANSACTIONS														
Sale, Disposition, or Transfer	B	S		B	B	O	ASSOC REG # CIVILDEF OFFICER RECALL B	H	O	O	B	B	B	B
Destroyed	B	Y		B	B	O	DEA REGIONAL REG # B		O	O	B	B	B	B
Theft	B	T		B	B	O			O	O	B	B	B	B
Non-recov. Waste	B	N		B	B	O			O	O	B	B	B	B
Used in Production	B	U		B	B	O			O	O	B	B	B	B

B Mandatory.
C Normally: Associate Registrant Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSELS, NATIVE, & MILITARY.
* Normally: Associate Registrant Number or UNKNOWN.
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

Transaction	Reporting Registrant (1)	Trans. Code (2)	Action Indicator (3)	NDC (4)	Quantity (5)	Unit (6)	Associate Registrant (7)	Order Form Number (8)	Correction Number (9)	Strength (10)	Trans. Date, Yr (11)	Trans. Date, Mo (12)	Trans. Date,Day (13)	Tranced (14)
Used in Preparation	B	K		B	B	O			O	O	B	B	B	B
Receipt by Government or Seizure	B	Z		B	B	O	DEA/FDA #, Officer B		O	O	B	B	B	B
Sampling	B	Q		B	B	O			O	O	B	B	B	B
DELETION, ADJUSTMENT, AND LATE TRANSACTIONS														
Deletion	B	B	D	Fields 2 and 4-14: Enter the same information as was entered on the original transaction.										
Adjustment	B	B	A	Fields 4-14: Enter the original information for unchanged fields and the revised information for changed fields.										
Late	B	B	I	Fields 4-14: Enter normal transaction information.										
MISCELLANEOUS TRANSACTIONS														
No Activity	B	7							O		B	B	B	B
Lost-in-Transit	B	X		B	B	O	B	H	O	O	B	B	B	B
Order DEA Form 333	B	F			O				O		B	B	B	B

B Mandatory.
C Normally: Associate Registrant Number or Regional DEA or FDA Registration Number. Unusual situations: OFFICER, CIVILDEF, VESSELS, NATIVE, & MILITARY.
***** Normally: Associate Registrant Number or UNKNOWN.
O Optional, depending upon quantity entered: Fields 6 and 10: Mandatory for all transactions reporting Bulk Raw Materials.
H Mandatory for Schedules I and II products. ( ): Indicates Field Numbers

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APPENDIX 3

CONVERSION FACTORS FOR CONTROLLED SUBSTANCES (FROM SALT TO ANHYDROUS BASE OR ACID)

11-HYDROXY DELTA-9 TETRAHYDROCANNABINOL	0.9595
2,5-DIMETHOXYAMPHETAMINE HCL(2,5-DMA)	0.8427
(-)2 -CARBOMETHOXY-3 -(4-FLUOROPHENYL)TROPANE	0.3275
3,4-METHYLENEDIOXYAMPHET ACETATE	0.7491
3,4-METHYLENEDIOXYAMPHET HCL	0.8310
3,4-METHYLENEDIOXYAMPHET S04	0.6463
4-ETHYL-2,5-DIMETHOXYAMPHET HCL(DOET.HCL)	0.8598
4-METHOXYAMPHETAMINE HCL(PMA)	0.8190
4-METHYL-2,5-DIMETHOXYAMPHET HCL(STP OR DOM)	0.8586
ALFENTANIL HYDROCHLORIDE	0.9280
ALPHA-ETHYL TRYPTAMINE ACETATE	0.7584
ALPHAMETHADOL HYDROCHLORIDE	0.8952
ALPHANORMETHADOL HCL	0.8952
ALPHAPRODINE HYDROCHLORIDE	0.8776
ALPHENAL SODIUM	0.9174
AMINOPROPYLMORPHINE	0.8333
AMOBARBITAL SODIUM	0.9114
AMPHETAMINE HYDROIODIDE	0.5515
ANILERIDINE DIHYDROCHLORIDE	0.8286
ANILERIDINE PHOSPHATE	0.7825
APROBARBITAL SODIUM	0.9052
BARBITAL SODIUM	0.8933
BENZPHETAMINE HYDROCHLORIDE	0.8678
BETAPRODINE MALATE	0.6609
BUFOTENINE MONOOXOLATE.H20	0.6538
BUPRENORPHINE HYDROCHLORIDE	0.9275
BUTABARBITAL SODIUM	0.9062
BUTALBITAL SODIUM	0.8549
BUTALLYLONAL SODIUM	0.9295
CANNABINOL ACETATE	0.8807
CATHINONE HCL	0.8036
CHLORAL BETAINE	0.5216
CHLORAL HYDRATE	0.8911
CHLORDIAZEPOXIDE HYDROCHLORIDE	0.8916
CHLORPHENTERMINE.HCL	0.8344
CLORAZEPATE DIPOTASSIUM	0.8137
CLORAZEPATE MONOPOTASSIUM	0.8924
CLORTERMINE.HCL	0.8344
COCAINE HYDROCHLORIDE	0.8927
COCAINE NITRATE	0.8280
COCAINE AMINO	0.9528
COCAINE-D3(DEUTERATED)	0.9903
CODEINE ACETATE	0.8329
CODEINE HYDROCHLORIDE	0.8914

CODEINE METHYLBROMIDE	0.7592
CODEINE PHOSPHATE.1/2H20	0.7367
CODEINE SULFATE.3H20	0.7974
CODEINE-6-GLUCURONIDE	0.6296
CODEINE-D3(DEUTERATED)	0.9900
CODEINE-N-OXIDE	0.9493
CYCLOBARBITAL CALCIUM	0.9255
CYPRENORPHINE HYDROCHLORIDE	0.9207
D-AMPHETAMINE ADIPATE	0.4807
D-AMPHETAMINE CARBOXYMETHYLCELLULOSE SALT	0.2593
D-AMPHETAMINE HYDROCHLORIDE	0.7876
D-AMPHETAMINE P04,DIBASIC	0.7340
D-AMPHETAMINE P04,MONOBASIC	0.5798
D-AMPHETAMINE SACCHARATE	0.3915
D-AMPHETAMINE S04.DIBASIC	0.7338
D-AMPHETAMINE SULFATE MONOBASIC	0.5796
D-AMPHETAMINE TANNATE	0.2956
D-EPHEDRINE HCL	0.8192
D-METHAMPHETAMINE HI	0.5385
D-METHAMPHETAMINE HYDROBROMIDE	0.6688
D-METHAMPHETAMINE HYDROCHLORIDE	0.8037
D-METHAMPHETAMINE SACCHARATE	0.4153
D-METHAMPHETAMINE SULFATE	0.7527
D-PSEUDOEPHEDRINE HCL	0.8192
DESOMORPHINE HYDROCHLORIDE	0.8816
DEXTROMORAMIDE BITARTRATE	0.7233
DEXTROMORAMIDE HYDROCHLORIDE	0.9150
DEXTROPROPOXYPHENE HYDROCHLORIDE	0.9030
DEXTROPROPOXYPHENE NAPSYLATE	0.6001
DIETHYLPROPION HYDROCHLORIDE	0.8492
DIETHYLTRYPTAMINE HYDROCHLORIDE	0.8556
DIFENOXIN HYDROCHLORIDE	0.9208
DIHYDROCODEINE BITARTRATE	0.6675
DIHYDROHYDROXYCODEINONE HYDROCHLORIDE	0.8964
DIHYDROMORPHINONE SULFATE	0.8533
DIMETHYLTRYPTAMINE FUMURATE	0.6230
DIPHENOXYLATE HYDROCHLORIDE	0.9254
DIPRENORPHINE HYDROCHLORIDE	0.9051
DIPROPYLTRYPTAMINE HYDROCHLORIDE	0.8720
DL-2-METHOXY-4,5-METHYLENEDIOXYAMPHETAMINE HCL	0.8518
DL-AMPHETAMINE ADIPATE	0.4806
DL-AMPHETAMINE ASPARTATE	0.5039
DL-AMPHETAMINE HYDROCHLORIDE	0.7876
DL-AMPHETAMINE P04,DIBASIC	0.7340
DL-AMPHETAMINE P04,MONOBASIC	0.5798
DL-AMPHETAMINE POSTASSIUM SACCHARATE	0.3526
DL-AMPHETAMINE SULFATE DIBASIC	0.7338
DL-AMPHETAMINE SULFATE MONOBASIC	0.5796
DL-AMPHETAMINE TANNATE	0.2956

DL-AMPHETAMINE-D11(DEUTERATED)	0.9243
DL-AMPHETAMINE-D6(DEUTERATERD)	0.9572
DL-EPHEDRINE HCL	0.8192
DL-METHAMPHETAMINE HI	0.5385
DL-METHAMPHETAMINE HYDROCHLORIDE	0.8037
DL-METHAMPHETAMINE-D9(DEUTERATED)	0.9428
DL-METHAMPHETAMINE-D9(DEUTERATED)	0.9428
DL-PSEUDOEPHEDRINE HCL	0.8192
ECGONINE BENZOATE-D3 (DEUTERATED)	0.6336
ECGONINE BENZOATE-D3-.4H20	0.5083
ECGONINE BENZOYLPROPYLESTER	0.5589
ECGONINE BENZOYLPROPYLESTER HCL	0.5035
ECOGONINE BENZOATE, ANHYDROUS	0.6402
ETHYLMORPHINE HYDROCHLORIDE	0.8121
ETHYLMORPHINE METHYLIODIDE	0.6883
ETICYCLIDINE HYDROCHLDRIDE(ETHYLAMINE ANOLOG)	0.8480
ETONITAZENE HYDROCHLORIDE	0.9158
ETORPHINE HCL	0.9186
FENCAMFAMIN HYDROCHLORIDE	0.8552
FENFLURAMINE HYDROCHLORIDE	0.8638
FENTANYL CITRATE	0.6365
FENTANYL HYDROCHLORIDE	0.9022
FLURAZEPAM HYDROCHLORIDE	0.8418
HEROIN HYDROCHLORIDE BROWN	0.9102
HEROIN HYDROCHLORIDE WHITE	0.9102
HEXETHAL SODIUM	0.9161
HEXOBARBITAL SODIUM	0.9148
HYDROCODONS BITARTRATE	0.6054
HYDROCODONE TEREPHTHALATE	0.6431
HYDROCODONE-D3(DEUTERATED)	0.9900
HYDROCODONE-D6(DEUTERATED)	0.9802
HYDROMORPHINOL BITARTRATE	0.6435
HYDROMORPHONE HYDROCHLORIDE	0.8867
HYDROMORPHONE-D3(DEUTERATED)	0.9895
IBOGAINE HYDROCHLORIDE	0.8948
KETAMINE HYDROCHLORIDE	0.8670
L-EPHEDRINE HCL	0.8192
L-PSEUDOEPHEDRINE HCL	0.8192
LEVALPHAACETYLMETHADOL.HCL(LAAM.HCL)	0.9065
LEVAMPHETAMINE MUCATE	0.5338
LEVAMPHETAMINE P-AMINOBENZOATE	0.5254
LEVAMPHETAMINE S04 DIBASIC	0.7338
LEVAMPHETANINE SUCCINATE	0.5337
LEVMETHAMPHETAMINE HYDROCHLODIDE	0.8037
LEVORPHANOL HBR	0.7608
LEVORPHANOL HCL	0.8759
LEVORPHANOL TARTRATE	0.5803
LYSIGERIDE TARTRATE(D-LSD TART.)	0.8117
MBDB.HCL (N-CH3-1-(3,4-METHYLENEDIOXYPHENYL) -2-BUTANAMINE.HCL)	0.8505
MDE.HCL	

(N-ETHYL-3,4-METHYLENEDIOXYAMPHETAMINE.HCL)	0.8504
MECLOQUALONE HYDROCHLORIDE	0.8813
MEFENOREX HYDROCHLORIDE	0.8531
MEPERIDINE HCL	0.8715
MEPERIDINE INTERMEDIATE B HYDROBROMIDE	0.7535
MEPERIDINE-D4(DEUTERATED)	0.9838
MEPHOBARBITAL SODIUM	0.9146
MESCALINE ACID SULFATE	0.6829
MESCALINE HYDROCHLORIDE	0.8528
MESCALINE SULFATE	0.3922
META-OH BENZOYL ECGONINE	0.6066
METHADONE HYDROBROMIDE	0.7922
METHADONE HYDROCHLORIDE	0.8946
METHAQUALONE HYDROCHLORIDE	0.8729
METHAQUALONE-D7(DEUTERATED)	0.9726
METHARBITAL SODIUM	0.9002
METHCATHINONE HCL	0.8174
METHOHEXITAL SODIUM	0.9226
METHYLPHENIDATE HYDROCHLORIDE	0.8648
METHYLPHENIDATE-D3(DEUTERATED)	0.9872
METHYLPHENIDATE-D3-HCL(DEUTERATED SALT)	0.8552
METOPON HYDROCHLORIDE	0.8914
MIDAZOLAM HCL	0.8969
MORPHINE ACETATE	0.7144
MORPHINE HYDROBROMIDE	0.7790
MORPHINE HYDROCHLORIDE	0.8866
MORPHINE NITRATE	0.8191
MORPHINE PHOSPHATE,MONO	0.7444
MORPHINE SULFATE PENTAHYDRATE	0.7521
MORPHINE, MONOHYDRATE	0.9405
MORPHINE-3-ETHEREAL SULFATE	0.7809
MORPHINE-3-GLUCURONIDE	0.6183
MORPHINE-3-GLUCURONIDE(D3)	0.6143
MORPHINE-D3(DEUTERATED)	0.9895
N-OH-3,4 METHYLENEDIOXYAMPHET HCL	0.8426
NALBUPHINE HCL	0.9074
NALMEFENE HYDROCHLORIDE	0.9030
NALORPHINE HYDROCHLORIDE	0.8952
NALTREXONE HYDROCHLORIDE	0.9035
NORACYMETHADOL HYDROCHLORIDE	0.9030
NORCODEINE HYDROCHLORIDE	0.7592
NOREGONINE	1.0820
NORMORPHINE HYDROCHLORIDE	0.8328
NOROXYMORPHONE HYDROCHLORIDE	0.8808
OXYCODONE HYDROCHLORIDE	0.8964
OXYCODONE TEREPHTRALATE	0.7915

OXYMORPHONE HCL,MONOHYDRATE	0.8469	
OXYMORPHONE HYDROCHLORIDE	0.8921	
PENTAZOCINE HCL	0.8867	
PENTAZOCINE LACTATE	0.7601	
PENTOBARBITAL CALCIUM	0.8496	
PENTOBARBITAL SODIUM	0.9114	
PHENAZOCINE HYDROBROMIDE	0.7989	
PHENCYCLIDINE HYDROCHLORIDE(PCP-HCL)	0.8697	
PHENCYCLIDINE,DEUTERATED	0.9798	
PHENDINETRAZINE HYDROCHLORIDE	0.8399	
PHENDIMETRAZINE TARTRATE	0.5603	
PHENMETRAZINE HYDROCHLORIDE	0.8294	
PHENOBARBITAL CALCIUM	0.8528	
PHENOBARBITAL SODIUM	0.9136	
PHENTERMINE HYDROCHLORIDE	0.8037	
PHENYLPROPANOLAMINE HCL	0.8057	
PIMINODINE ESYLATE	0.7689	
PIMINODINE ETHANESULFONATE	0.7689	
PIPERIDINE HYDROCHLORIDE	0.7002	
PIPERIDINE PHOSPHATE	0.4649	
PIPRADOL HYDROCHLORIDE	0.8800	
PROBARBITAL CALCIUM	0.8115	
PROBARBITAL SODIUM	0.9001	
PROPIRAM FUMARATE	0.7035	
PSEUDOMORPHINE HYDROCHLORIDE	0.9398	
PYROVALERONE HYDROCHLORIDE	0.8706	
RACEMORPHAN HYDROBROMIDE	0.7607	
ROLICYCLIDINE HYRDOCHLORIDE(PYRROLIDINE ANALOG)		0.8692
SECOBARBITAL SODIUM	0.9155	
SUFENTANIL CITRATE	0.6680	
TENOCYCLIDINE HYDRO CHLORIDE(TCP-HCL),THIOPHENE ANALOG	0.8726	
THEBAINE BITARTRATE	0.6494	
THEBAINE HYDROCHLORIDE	0.8510	
THIALBARBITAL SODIUM	0.9232	
THIANYLAL SODIUM	0.9204	
THIOPENTAL SODIUM	0.9167	
TROPACOCAINE HYDROCHLORIDE	0.8706	
VINBARBITAL SODIUM	0.9107	
ZOLPIDEM BITARTRATE	0.8038	

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APPENDIX 4

USE of QUANTITY, UNIT, and STRENGTH FIELDS

NDC NUMBER	PACKAGE DESCRIPTION	**QUANTITY**	**UNIT**	**STRENGTH**	**DESCRIPTION of ITEM(S) REPORTED**
12345-6789-04	4 fl oz Bottle	00000001			1 Bottle of 4 fl oz.
12345-6789-04	4 fl oz Bottle	00000015			15 Each 4 fl oz Bottles (60 fl oz).
12345-6789-04	4 fl oz Bottle	00000001		0750	1 partial Bottle of 3 fl oz (75% of 4 fl oz).
01234-0002-01	Bottle of 500 Tabs	00000002	D		2 Dozen Bottles @ 500 Tabs each (12,000 Tabs).
01234-0003-01	Bottle of 100 Caps	00000001		0900	1 Bottle of 90 Caps (90% of a Package).
01234-0003-01	Bottle of 100 Caps	00000001		1150	115.0% of 100 equals 115 Caps (one full bottle of 100 plus a partial bottle of 15) .
01234-9999-01	5ml Amp Injection	00000001			5ml Ampule.
01234-9999-01	5ml Amp Injection	00000005			5 each 5ml Ampules (25ml).
01234-9999-02	Box of 10 each 5ml Ampules (Injection)	00000001			1 box of 10 each 5ml Ampules (50ml).
01234-9999-02	Box of 10 each 5ml Ampules (Injection)	00000010			10 boxes of 10 each 5ml Ampules (500ml).
12345-0001-**	Unpackaged Bulk Tabs	00000001			1 Tab.
12345-0001-**	Unpackaged Bulk Tabs	00000001	K		1,000 Tabs.
12345-0002-**	**RAW Bulk Powder**[+]	00000012	3[++]	1000[++]	12gms of Bulk Powder @ 100.0% purity.
12345-0003-**	Unpackaged Bulk Liquid	00000850	5		850 ml of Bulk Liquid.
12345-0003-**	Unpackaged Bulk Liquid	00000010	6		10 liters of Bulk Liquid.
12345-0004-**	Unpackaged Bulk Beads	00000010	3		10gms of Bulk Beads (Intermediate)
12345-0004-**	Unpackaged Bulk Beads	00000001	4		4kgs of Bulk Beads (Intermediate)

NOTES: [+] For ARCOS transactions, the STRENGTH and UNIT fields must be completed when reporting NDC's designated as RAW Bulk in the ARCOS NDC Dictionary.
[++] Mandatory Field.
UNIT Field Values: K=Thousands, D= Dozens, 1=Micrograms, 2=Milligrams, 3=Grams, 4=Kilograms, 5=Milliliters, 6=Liters

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APPENDIX 5

ARCOS RECORD: DATA FIELDS AND CALCULATIONS

NDC Pkg. Code (1)	Trans. Record Quantity Field (2)	Unit Field (3)	Strength Field (4)	Inventory Quantity (5)	Inventory Quantity X Ingredient weight (6)
Numeric or Alpha	Numeric	Blank	Numeric (Partial Pkg.)	Quantity X Pkg.% if applicable	Qty of DU's to Grams
	Numeric	Blank	Blank	Quantity	Qty of DU's to Grams
		D	Blank	Quantity x 12	Qty of DU's to Grams
		K	Blank	Quantity x 1000	Qty of DU's to Grams
**(RAW) Bulk Powder	Numeric	1	Numeric	Quantity X .000001 x Strength	Micrograms to Grams
		2	"	Quantity X .001 x Strength	Milligrams to Grams
		3	"	Quantity X Strength	Grams to Grams
		4	"	Quantity X 1000 X Strength	Kilograms to Grams
		5	"	Quantity X 1 X Strength	Milliliters to Grams
		6	"	Quantity X 1000 X Strength	Liters to Grams
** (Unpackaged, Bulk Dosage Units)	Numeric	Blank	Blank	Quantity	Qty of DU's to Grams
		D	"	Quantity X 12	Qty of DU's to Grams
		K	"	Quantity X 1000	Qty of DU's to Grams
		1	"	Quantity X .000001	Micrograms to Grams
		2	"	Quantity X .001	Milligrams to Grams
		3	"	Quantity X 1	Grams to Grams
		4	"	Quantity X 1000	Kilograms to Grams
		5	"	Quantity X 1	Milliliters to Grams
		6	"	Quantity X 1000	Liters to Grams

This chart demonstrates the procedure employed by the ARCOS system in calculating the quantity of controlled substance in a reported ARCOS transaction.

Column (1)
NDC Package Code, identifies three basic types of NDC products

Column (2)
Transaction Record Quantity Field, specifies the amount (i.e., quantity) of the NDC product involved in the ARCOS activity (i.e., transaction)

Column (3)
Unit Field, identifies specific coding designations that reflect the size (D,K); weight (1, 2, 3, 4); or volume (5, 6) associated with the reported NDC product.

Column (4)
Strength Field, reflects: (a) the purity of the controlled drug substance contained in the NDC product or (b) a percentage of the NDC product's trade package being reported.

Column (5)
Inventory Quantity, illustrates algorithms used by the ARCOS software

Column (6)
Inventory Quantity X Ingredient Weight, identifies the final gram conversion of the controlled drug substance contained in the reported NDC product by taking into account any effect of quantity, unit and strength information. The resulting figure is multiplied by the ingredient weight data of the specific NDC product involved in the reported transaction. The ingredient weight of the controlled substance in the NDC product is contained in the ARCOS drug ingredient dictionary.

KEY:
“Blank” indicates there is no entry.
DU = dosage unit (capsule, tablet, etc.)
D = Dozen
K = Thousands