ATTACHMENT E: THE 1988 GUIDANCE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date: AUG 1 1988

re: Prescription Drug
Marketing Act of 1987

[Docket No. 88N-258L]

TO REGULATED INDUSTRY AND OTHER INTERESTED PERSONS

Dear Sir or Madam:

The purpose of this letter is to provide you information on the Prescription Drug Marketing Act of 1987 [Pub.L. 100-293, 102 STAT. 95], which was signed into law by the President on April 22, 1988.

The Food and Drug Administration (FDA) intends to propose rules, through notice and comment rulemaking, to implement this legislation. Until these rules are finalized, the information in this letter may be relied upon with assurance of its acceptability to FDA. This letter, however, is not intended to bind FDA should events occur prior to the issuance of a rule that require a change in FDA's policy. Changes in FDA policy will be announced in future letters or notices. In addition, except insofar as this letter describes legal requirements found in the legislation or existing regulations, this letter does not state legal requirements but, rather, FDA's interpretation of how the legislation should be implemented. (For example, use of the word "shall" indicates a legal requirement.)

I. BACKGROUND

The Prescription Drug Marketing Act of 1987 (the new law) amends the Federal Food, Drug, and Cosmetic Act (the Act) to: (1) require State licensing of wholesale distributors of prescription human drugs under Federal guidelines that include minimum standards for storage, handling, and recordkeeping; (2) ban the reimportation of prescription human drugs produced in the United States, except when reimported by the manufacturer or for emergency use; (3) ban the sale, trade, or purchase of drug samples; (4) ban trafficking in or counterfeiting of drug coupons; (5) mandate storage, handling, and recordkeeping requirements for drug samples; (6) require practitioners to request drug samples in writing; (7) prohibit, with certain exceptions, the resale of prescription human drugs purchased by hospitals or health care facilities; and (8) set forth criminal and civil penalties for violations of these provisions.

II. EFFECTIVE DATES

The effective date for most provisions of the new law is July 22, 1988, except that the requirements relating to the distribution of drug samples become effective on October 20, 1988, and the requirement for wholesale distributors to be licensed by the State becomes effective 2 years after the adoption of final rules by the Agency setting standards for State licensing. FDA is required to issue regulations establishing minimum guidelines for State licensing of wholesale distributors engaged in interstate commerce by October 20, 1988.

III. SCOPE

The new law applies to drugs subject to Section 503(b) of the Act — "prescription drugs."

"Prescription drug" may be interpreted to include any finished dosage form or active ingredient subject to Section 503(b) of the Act or any drug for human use required by Federal or State law or regulation to be dispensed only by a prescription.

"Active ingredient" may be interpreted to mean any drug or drug component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans.

IV. REIMPORTATION OF U.S.-MANUFACTURED DRUGS

Congress found that large amounts of prescription drugs are being reimported into the United States as American goods returned, and that these reimports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping. Accordingly, Congress amended Section 801 of the Act to prohibit the re-importation of U.S.-produced prescription drugs, except by the manufacturer of the product or as authorized by FDA for emergency purposes.

For the purpose of this letter, "manufacturer" may be interpreted to mean a person who is engaged in the manufacture, preparation, propagation, compounding, processing, packaging, or labeling of a drug or drugs, as used in Section 510 of the Act.

The Agency has issued an Import Alert (Import Alert #66-14) concerning reimportation of U.S.-manufactured prescription drugs. A copy of the Import Alert is attached to this letter. Applications to reimport prescription drugs for emergency medical care should be submitted to the

Director of the FDA District into which the person reimporting the drug is located (see 21 CFR 5.115). A list of FDA District Offices is attached to this letter.

V. DRUG SAMPLES AND DRUG COUPONS

The new law defines "drug sample" to mean a unit of a prescription drug which is not intended to be sold and is intended to promote the sale of the drug.

The new law defines "drug coupon" to mean a form which may be redeemed, at no cost or at a reduced cost, for a prescription drug.

Congress found that the existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades, and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals. In response to this problem, Congress amended Section 503 of the Act to prohibit sale, purchase, or trade of drug samples and drug coupons; the offer to sell, purchase, or trade drug samples and drug coupons; and the counterfeiting of drug coupons. The new law also includes in amended Section 503 specific requirements for the distribution of drug samples.

A. REQUIREMENTS FOR DRUG SAMPLE DISTRIBUTION BY MAIL OR COMMON CARRIER.

The manufacturer or distributor of a prescription drug may distribute prescription drug samples to a licensed practitioner—or to the pharmacy of a hospital or other health care entity at the request of a licensed practitioner—by mail or common carrier, provided that the licensed practitioner submits a written request setting forth certain specified information and the recipient of the drug sample executes a written receipt upon its delivery and returns the receipt to the manufacturer or distributor.

1. Submission of a written request for a drug sample for delivery by mail or common carrier. To request a drug sample for delivery by mail or common carrier, a practitioner shall submit a written request on a form setting forth the information required below:

(a) Name, address, professional designation, and signature of the practitioner making the request;
(b) The identity of the drug sample requested;
(c) The quantity requested;
(d) The name of the manufacturer of the drug sample requested; and
(e) The date of request.

2. Recordkeeping requirements for drug samples delivered by mail or common carrier. Each drug manufacturer or distributor who distributes samples by mail or common carrier shall maintain all sample request forms and all receipts for a period of 3 years, and shall maintain a drug sample distribution record identifying all drugs distributed and all

recipients of samples. These records shall be made available on request to FDA and other Federal, State, and local drug law enforcement officials by the manufacturer or distributor.

B. REQUIREMENTS FOR SAMPLE DISTRIBUTION BY REPRESENTATIVES

The manufacturer or distributor of a prescription drug may distribute prescription drug samples to a licensed practitioner—or to the pharmacy of a hospital or other health care entity at the request of a licensed practitioner—by means other than by mail or common carrier (e.g., by representatives or "detail persons"), provided that the manufacturer or distributor makes the distribution pursuant to a written request from a licensed practitioner setting forth certain information specified in paragraph 1 and carries out the activities specified in paragraphs 2 through 8.

1. Submission of written request for a drug sample for delivery by a representative. To request a drug sample for delivery by a representative, a practitioner shall submit a written request on a form setting forth the information required below:

(a) Name, address, professional designation, and signature of the practitioner making the request;
(b) The identity of the drug sample requested;
(c) The quantity requested;
(d) The name of the manufacturer or distributor of the drug sample requested; and
(e) The date of request.

2. Proper storage of drug samples. All drug samples shall be stored by manufacturers or distributors under conditions that will maintain their stability, integrity, and effectiveness, and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

3. Inventories of manufacturers' and distributors' representatives. Drug manufacturers or distributors shall conduct, at least annually, complete and accurate inventories of all drug samples in the possession of manufacturers' and distributors' representatives.

4. Lists of manufacturers' and distributors' representatives. Drug manufacturers or distributors shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored.

5. Maintenance of records. Drug manufacturers or distributors shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or distributor; of all inventories maintained under this section; of all thefts or significant losses of drug samples; and of all requests for drug samples under this section. Records and lists maintained under this section shall be made available on request to FDA by the manufacturer or distributor.

6. Notification of significant loss or theft. Drug manufacturers or distributors shall notify FDA of any significant loss of drug samples and any known theft of drug samples.

7. Notification if representative convicted of drug law violations. Drug manufacturers or distributors shall report to FDA any conviction of their representatives for violations of the prohibitions against sale of drug samples in Section 503(c)(1) of the Act or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

8. Name and telephone number of responsible person required. Drug manufacturers or distributors shall provide to FDA the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

C. GUIDANCE INFORMATION

1. "Licensed practitioner" may be interpreted to mean any person authorized by State law to prescribe prescription drugs.

2. Standing requests. FDA requests that separate written requests be made for each sample or group of samples, and that open-ended or "standing" requests not be used to order drug samples.

3. Forms for drug sample requests. Forms developed by manufacturers and distributors for manufacturers to request drug samples that comply with the above requirements are acceptable to FDA.

4. Drug Enforcement Administration (DEA) and State identification and license numbers. FDA requests that the request form for a drug sample include, if applicable, the Drug Enforcement Administration identification number and the State license number of the practitioner making the request.

5. Samples to hospitals or health care entities. The Agency requests that a licensed practitioner requesting delivery of a sample to a pharmacy of a hospital or health care entity include the name and address of the intended recipient on the request form. When a sample is requested to be delivered by mail or common carrier, FDA requests that the licensed practitioner requesting the sample include the name of the responsible party who will sign the receipt acknowledging delivery.

6. Receipts for samples delivered by mail or common carrier. U.S. Postal Service return receipts, business reply cards, or similar forms that produce written receipts are acceptable to FDA for the verification of delivery of samples shipped by mail or common carrier.

7. Verification of delivery of samples delivered by representatives. FDA requests that the manufacturer or distributor verify by written receipt the delivery of a drug sample by a detail person to a licensed practitioner or to the pharmacy of a hospital or health care entity receiving samples at the request of a licensed practitioner. The Agency requests that a practitioner, hospital, or health care entity who is sent a sample but fails to execute a receipt be barred from receiving additional samples.

8. Proper storage of drug samples distributed by representatives. Compliance by manufacturers, distributors, and representatives with 21 CFR 205.50(a) through (e) and 205.50(i), the storage and handling sections of the FDA guidelines for State wholesale distributor licensing, which will be published shortly, is acceptable assurance to FDA of good storage and handling practices for drug samples.

9. Inventories of manufacturer's and distributor's representatives. FDA requests that inventories be conducted by independent personnel. Discrepancies should be carefully evaluated and full investigations made when circumstances warrant. FDA requests that the inventory include the following:

(a) The name of the drug and the dosage strength,
(b) The date of each shipment,
(c) The recipient of the drug,
(d) The quantity of drug shipped,
(e) The quantity of drug received, and
(f) The quantity of the drug on hand.

10. When to notify FDA of a significant loss or theft of drug samples. The agency requests that it be notified within 5 working days when a manufacturer or distributor becomes aware of a significant loss or theft of drug samples.

11. Whom to notify at FDA of a significant loss or theft. When a significant loss of drug samples or a theft is identified, the drug manufacturer or distributor should notify the Office of Compliance (HFD-300), Center for Drug Evaluation and Research (CDER), or the Office of Compliance (HFB-100), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, as appropriate.

12. How to notify FDA of a significant loss or theft. The Agency will accept an initial notification by telephone, but asks that a telephone notification be followed by a written report as soon as practicable. A full report of any investigation into the loss or theft should be submitted in writing to the CDER or CBER Office of Compliance, as appropriate, upon completion. FDA may conduct an investigation regarding a significant loss or theft of drug samples.

13. Information leading to the conviction of a representative. FDA encourages reporting of information about suspected violations of Section 503(c)(1) or a State law regarding the sale, purchase, or trade of drug samples. A person or firm making such a report may be entitled to a reward if that information results in a conviction (see section VIII of this letter, Rewards).

14. How to report the conviction of a representative to FDA. The Agency requests that manufacturers and distributors report to the Office of Compliance in CDER or CBER, as appropriate, when one or more of their representatives is convicted of violating Section 503(c)(1) of the Act or any State law involving sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample. Such a report should be made within 30 days of such information becoming known to a manufacturer or distributor.

15. How to advise FDA of a drug sample contact person. The Agency requests that a drug manufacturer or distributor who intends to distribute drug samples other than by mail or common carrier provide to the Office of Compliance in CDER or CBER, as appropriate, the name and telephone number of the individual designated to respond to requests for information relating to drug samples.

VI. SALES RESTRICTIONS FOR HOSPITALS, HEALTH CARE ENTITIES, AND CERTAIN CHARITABLE ORGANIZATIONS

Congress found that bulk resale of below-wholesale priced prescription drugs by health care entities for ultimate sale at retail helps fuel the drug diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices. Accordingly, Congress amended Section 503 of the Act to prohibit the sale, purchase, or trade (and the offer to sell, purchase, or trade) of prescription drugs by a hospital or health care entity; or the sale, purchase, or trade of prescription drugs donated or sold at reduced cost to charitable institutions operating under section 501(c)(3) of the Internal Revenue Code of 1954 (except for a sale to a nonprofit affiliate of the charitable organization).

A. EXCEPTIONS

Section 503(c)(3)(B) of the Act provides certain exceptions to the sales restrictions provisions. They include:

1. The purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization;

2. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

3. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control;

4. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; and

5. The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a valid prescription.

B. GUIDANCE INFORMATION

1. "Health care entity" may be interpreted to mean any organization or business entity that provides diagnostic, medical, surgical, or dental treatment and/or care, or chronic and/or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under State law to deal in prescription drugs.

2. "Group purchasing organization" may be interpreted to mean any entity established, maintained, and operated for the purchase of drugs for distribution exclusively to its members with such membership consisting solely of health care entities bound by written contract with the organization.

3. The new law states that "emergency medical reasons" include transfers of a prescription drug between health care entities or from a health care entity to a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules.

4. "Nonprofit affiliate" may be interpreted to mean any not-for-profit organization that is either associated with or a subsidiary of a charitable organization as defined in Section 501(c)(3) of the Internal Revenue Code of 1954.

5. Blood and blood components. Blood and blood components intended for transfusion are biological products licensable under Section 351 of the Public Health Service Act (the PHS Act) as well as being prescription drugs. Such blood and blood components, including whole blood, red blood cells, plasma, and platelets, are usually collected and processed by blood establishments or "blood banks," and are used at hospital transfusion services. A unique public-private distribution system has

evolved under the Federally sponsored National Blood Policy, whereby blood establishments and medical facilities share blood resources to avoid wastage of blood and blood components. A unit of blood or blood component may be sent to a transfusion service to be held in case of an emergency, then be sent to another facility to balance a diminishing inventory, and pass through several facilities before the unit is ultimately transfused.

An extensive system of regulation of the blood supply now exists to protect the public against substandard, ineffective, or counterfeit blood and blood components. Storage and shipment of blood and blood components are carefully controlled by FDA regulation. FDA believes that prohibiting resale of blood and blood components as it now takes place freely among hospitals and blood establishments would severely inhibit the current system of blood resources distribution, could result in local shortages and undue wastage of blood, and could have an adverse effect on public health.

Under its enforcement discretion, FDA has concluded, pending notice and comment rulemaking, that it will not take compliance action against blood establishments or hospitals which engage in the sale, purchase, trade, transfer, exchange, credit, barter or other trafficking in blood and blood components, as defined at 21 CFR 606.3(a) and (c), for violating the sales restriction requirements of the new law.

6. Government hospitals and health care entities. Congress has established an extensive system of public hospitals and health care entities. These include the hospitals, clinics, and dispensaries operated for the military by the Department of Defense; hospitals and clinics operated by the Veterans Administration; and hospitals and clinics operated by the U.S. Public Health Service (including Indian Health Service hospitals and clinics).

In addition, State and local governments have established public health hospitals, clinics, and dispensaries, including drug treatment inpatient and outpatient facilities. These facilities operate under several varieties of organization and control. They may be owned and operated by governmental entities; they may be organized as private corporations or associations under contract to State or local government agencies; and they may be organized under public-private partnerships under informal or formal contractual arrangements with local governmental authorities. These health care entities may have inter-agency arrangements for the purchase and exchange of prescription drugs. Such facilities operate because of Federal or State governmental commitments to provide certain kinds of health care to particular classes of patients in response to specific client needs. FDA believes that it would be unwise to unduly interfere with the established patterns of operation of these governmentally mandated health care facilities.

Under its enforcement discretion, FDA has concluded, pending notice and comment rulemaking, that it will not take compliance action against government hospitals or health care entities which engage in the sale, purchase, trade, transfer, exchange, credit, barter, or other trafficking in prescription drugs (including vaccines and other biological drugs) with other government hospitals and health care entities for violations of the sales restrictions of the new law.

7. Returns by hospitals, health care entities, and charitable institutions. A return of a prescription drug to a manufacturer or distributor by a hospital, health care entity, or charitable institution may be interpreted as falling outside the scope of a sale or trade, provided that:

(a) The return is made directly to the manufacturer, and the manufacturer notifies the person returning the product in writing that the returned prescription drug was received; or

(b) The return is made to a wholesale distributor, and the person returning the product receives a written statement from the manufacturer that the returned prescription drug was either destroyed by the wholesaler or forwarded to and received by the manufacturer.

VII. WHOLESALE DISTRIBUTION

Congress found that the existence and operation of a wholesale submarket, commonly known as the "diversion market," prevents effective control over or even routine knowledge of the true sources of prescription drugs for human use in a significant number of cases. Accordingly, Congress amended Section 503 of the Act by adding new paragraph 503(e), which regulates wholesale distribution of prescription drug products.

The new law defines "wholesale distribution" as the distribution of drugs subject to Section 503(b) of the Act to other than the consumer or patient, but does not include intracompany sales or the following distributions of prescription drugs:

(a) The purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization;

(b) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(c) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities which are under common control;

(d) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons; or

(e) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug pursuant to a prescription executed in accordance with Section 503(b) of the Act.

A. REQUIREMENTS AFFECTING ALL WHOLESALE DISTRIBUTORS

Section 503(e)(2) prohibits the wholesale distribution of prescription drugs in interstate commerce unless the wholesale distributor is licensed by the State in accordance with Federally prescribed minimum standards, conditions, and terms, as set forth in guidelines to be issued by the FDA. These minimum standards, conditions, and terms are to include minimum requirements for storage, handling, and recordkeeping.

Section 503(e)(2) requires that the guidelines be promulgated as a regulation, through notice and comment rulemaking. The prohibition against distribution of prescription drugs by unlicensed wholesalers becomes effective 2 years after the final regulation setting forth the Federal guideline is published by the Agency in the FEDERAL REGISTER. FDA intends to implement Section 503(e)(2) shortly.

B. REQUIREMENTS FOR UNAUTHORIZED DISTRIBUTORS

Section 503(e)(1) requires that a person who is engaged in the wholesale distribution of prescription drugs and who is not an authorized distributor of record of such drugs shall provide to each wholesale distributor of such drugs a statement identifying each sale of the drug (including the date of sale) before the sale to such wholesale distributor. The Act also provides that each manufacturer shall maintain a current list of authorized distributors at its corporate offices.

The new law defines "authorized distributors of record" as those distributors with whom the manufacturer has established an ongoing relationship to distribute such manufacturer's products.

C. GUIDANCE INFORMATION

1. "Wholesale distributor" may be interpreted to mean any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; manufacturers' and distributors' representatives; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. A transfer of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage may be interpreted not to be a wholesale distribution.

2. "Authorized distributors of record" may include, but would not be limited to, subsidiaries, franchisees, and distributors to whom the manufacturer distributes prescription drugs.

3. "Ongoing relationship," as used in the definition of "authorized distributors of record," may be interpreted to mean a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturer's prescription drug product or products. Evidence of such intent would include, but not be limited to, the existence of a written franchise, license, or other distribution agreement between the manufacturer and wholesale distributor; and the existence of ongoing sales by the manufacturer to the distributor, either directly or through a jointly agreed upon intermediary. The Agency would consider two transactions in any 24-month period to be evidence of a continuing relationship.

4. "Unauthorized distributor" may be interpreted to mean a distributor with whom the manufacturer has not established an ongoing relationship to distribute such manufacturer's products.

5. Statement identifying prior sales. FDA requests that the statement identifying prior sales of prescription drugs by unauthorized distributors be in writing, that it bear the title "Statement Identifying Prior Sales of Prescription Drugs by Unauthorized Distributors Required by the Prescription Drug Marketing Act," and that it include all necessary identifying information regarding all sales in the chain of distribution of the product, starting with the manufacturer or authorized distributor of record. FDA also requests that the identifying statement accompany all products purchased from an unauthorized distributor, even when they are resold. Identifying statements are not required to include information about sales completed before July 22, 1988. FDA requests that the identifying statement include the following information:

(a) The business name and address of the source from which the drug was purchased,

(b) The date of the sale, and

(c) The identity, strength, container size, number of containers, and lot number(s) of the drug.

6. Forms for identifying statements. Forms developed by manufacturers and distributors for identifying statements that comply with the above requirements will be acceptable to FDA.

7. Identifying statements recordkeeping. The Agency requests that the identifying statements be retained in a secure manner by each party to the transaction for a period of 3 years after the expiration date of the drug involved, and that they be made available for inspection or photocopying on request to authorized representatives of Federal, State, and local agencies with drug law enforcement responsibilities. Statements should be maintained at the place of business, except that records may be kept at the principal domestic business office of an entity that conducts business in multiple locations.

8. Manufacturer's list of authorized distributors of record. The Agency requests that the manufacturer's list of authorized distributors of record be made available upon request to authorized representatives of Federal, State, and local agencies with drug law enforcement responsibilities. The Agency also requests that such list be made available at reasonable charge to any person requesting it.

VIII. REWARDS

The new law provides for a reward for information leading to the arrest and conviction of a person who sells, purchases, or trades drug samples or coupons. The reward is one-half the criminal fine imposed and collected, not to exceed $125,000. A person wishing to provide information intended to lead to the arrest and conviction of a person for such a violation may make a report to the Office of Compliance in CDER or CBER, as appropriate.

IX. REQUESTS FOR INFORMATION FROM FDA

Requests for further information about the Prescription Drug Marketing Act of 1987 or for clarifications of the new law should be directed to the Division of Regulatory Affairs (HFD-360), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: 301-295-8038.

X. COMMENTS

FDA is seeking comments on implementation of the Prescription Drug Marketing Act of 1987 and this letter. Comments should be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857 (telephone 301/443-1751), identifying your comments with the docket number to be

found on the cover page of this letter. Please send comments to the Agency by September 30, 1988. Comments and other information in the docket will be available for review in that office during regular business hours, 9 a.m. to 4:30 p.m., Monday through Friday.

We hope the information in this letter is helpful in guiding affected persons seeking to comply with the new law. We are looking forward to seeing your comments and using them in developing FDA's implementing regulations.

Sincerely yours,

Daniel L. Michels
Director
Office of Compliance (HFD-300)
Center for Drug Evaluation and
Research

Sincerely yours,

for Thomas S. Bozzo
Director
Office of Compliance (HFB-100)
Center for Biologics Evaluation
and Research

ATTACHMENTS:
List of FDA District Offices
Import Alert #66-14

FINDING AID