VII. Submission Requirements

The original and two copies of the completed Grant Application Form PHS 398 (Rev. 4/98) with copies of the appendices for each of the copies, should be submitted to Maura Stephanos (address above). Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

VIII. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: July 10, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–18290 Filed 7–19–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94D–0325]

International Conference on Harmonisation; Draft Revised Guidance on Impurities in New Drug Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft revised guidance entitled ''Q3A(R) Impurities in New Drug Substances.'' The draft revised guidance, which updates a guidance on the same topic published in the **Federal Register** of January 4, 1996 (the 1996 guidance), was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft revised guidance clarifies the 1996 guidance, adds information, and provides consistency with more recently published ICH guidances. The draft revised guidance is intended to provide guidance to applicants for drug marketing registration on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in a country, region, or member State.

DATES: Submit written comments by September 18, 2000.

ADDRESSES: Submit written comments on the draft revised guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft revised guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852, or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Charles P. Hoiberg, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5169.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In October 1999, the ICH Steering Committee agreed that a draft revised guidance entitled ''Q3A(R) Impurities in New Drug Substances'' should be made available for public comment. The draft revised guidance is a revision of a guidance on the same topic published in the **Federal Register** of January 4, 1996 (61 FR 372). The draft revised guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

In accordance with FDA's good guidance practices (62 FR 8961, February 27, 1997), this document is now being called a guidance, rather than a guideline.

The draft revised guidance is intended to provide guidance to applicants for drug marketing registration on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in a country, region, or member State. The draft revised guidance is not intended to apply to new drug substances used during the clinical research stage of development or clinical trials. The draft revised guidance also does not apply to biological/biotechnological substances, peptides, oligonucleotides,

radiopharmaceuticals, fermentation and semisynthetic products derived from that process, herbal products, and crude products of animal or plant origin. Impurities in new drug substances are addressed in the draft revised guidance from two different perspectives: (1) Chemistry aspects—classification and identification of impurities, report generation, setting specifications, and a brief discussion of analytical procedures; and (2) safety aspects—guidance for qualifying impurities that were not present in batches of the new drug substance used in safety and clinical studies and/or impurity levels substantially higher than in those batches.

The draft revised guidance includes revised text on threshold limits, revised text on specification limits for impurities, and new guidance on rounding. Additions to the glossary include definitions for the terms ''identification threshold,'' ''qualification threshold,'' ''reporting threshold,'' and ''rounding.'' References to validated limit of quantitation were removed. The section on solvents references a more recently published ICH guidance entitled ''Q3C Impurities: Residual Solvents.'' Minor editorial changes were made to improve the clarity and consistency of the document.

This draft revised guidance represents the agency's current thinking on impurities in new drug substances. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft revised guidance by September 18, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft revised guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm.

The text of the draft revised guidance follows:

Q3A(R) Impurities in New Drug Substances [1]

1. Preamble

This document is intended to provide guidance for registration applications on the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered in a region or member State. It is not intended to apply to the regulation of new drug substances used during the clinical research stage of development. Biological/biotechnological, peptide, oligonucleotide, radiopharmaceutical, fermentation and semisynthetic products derived therefrom, herbal products, and crude products of animal or plant origin are not covered.

Impurities in new drug substances are addressed from two perspectives:

Chemistry aspects include classification and identification of impurities, report generation, setting specifications, and a brief discussion of analytical procedures; and

Safety aspects include specific guidance for qualifying impurities that were not present in batches of new drug substance used in safety and clinical studies and/or impurity levels substantially higher than in those batches. Threshold limits are defined, at or below which qualification is not needed.

2. Classification of Impurities

Impurities may be classified into the following categories:

- Organic Impurities (Process- and Drug-Related)
- Inorganic Impurities
- Residual Solvents

Organic impurities may arise during the manufacturing process and/or storage of the new drug substance. They may be identified or unidentified, volatile or nonvolatile, and include:

- Starting Materials
- By-Products
- Intermediates
- Degradation Products
- Reagents, Ligands, and Catalysts

Inorganic impurities may derive from the manufacturing process. They are normally known and identified, and include:

- Reagents, Ligands, and Catalysts
- Heavy Metals or Other Residual Metals
- Inorganic Salts

Solvents are organic or inorganic liquids used during the manufacturing process. Since these are generally of known toxicity, the selection of appropriate controls is easily accomplished (see ICH Q3C Impurities: Residual Solvents).

Excluded from this document are: Extraneous contaminants (other materials such as filter aids, charcoal) that should not occur in new drug substances and are more appropriately addressed as good manufacturing practice (GMP) issues; polymorphic form, a solid state property of the new drug substance; and enantiomeric impurities.

[1] This draft revised guidance represents the agency's current thinking on impurities in new drug substances. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

3. Rationale for the Reporting and Control of Impurities

3.1 Organic Impurities

The applicant should summarize those actual and potential impurities most likely to arise during the synthesis, purification, and storage of the new drug substance. This summary should be based on sound scientific appraisal of the chemical reactions involved in the synthesis, impurities associated with raw materials that could contribute to the impurity profile of the new drug substance, and possible degradation products. This discussion may include only those impurities that may reasonably be expected based on knowledge of the chemical reactions and conditions involved.

In addition, the applicant should summarize the laboratory studies conducted to detect impurities in the new drug substance. This summary should include test results of batches manufactured during the development process and batches from the proposed commercial process, as well as results of intentional degradation studies used to identify potential impurities arising during storage. Assessment of the proposed commercial process may be deferred until the first batch is produced for marketing. The impurity profile of the drug substance lots intended for marketing should be compared with those used in development, and any differences discussed.

The studies conducted to characterize the structure of actual impurities present in the new drug substance at a level greater than (>) the threshold given in Attachment 1 (e.g., calculated using the response factor of the drug substance) should be described. Note that all specified impurities at a level greater than (>) the identification threshold in batches manufactured by the proposed commercial process should be identified. Degradation products observed in stability studies at recommended storage conditions should be similarly identified. When identification of an impurity is not feasible, a summary of the laboratory studies demonstrating the unsuccessful effort should be included in the application. Where attempts have been made to identify impurities present at levels of not more than (≤) the identification thresholds, it is useful to also report the results of these studies.

Identification of impurities present at an apparent level of not more than (≤) the identification threshold is generally not necessary. However, analytical procedures should be developed for those potential impurities that are expected to be unusually potent, producing toxic or pharmacologic effects at a level less than or equal to (≤) the identification threshold. All impurities should be qualified as described later in this guidance. Conventional rounding rules should be applied, and the results presented with the same number of decimals as given in the limit (see glossary).

3.2 Inorganic Impurities

Inorganic impurities are normally detected and quantitated using pharmacopoeial or other appropriate procedures. Carryover of catalysts to the new drug substance should be evaluated during development. The need for

inclusion or exclusion of inorganic impurities in the new drug substance specifications should be discussed. Limits should be based on pharmacopoeial standards or known safety data.

3.3 Solvents

The control of residues of the solvents used in the manufacturing process for the new drug substance should be discussed and presented according to the ICH Q3C guidance for residual solvents.

4. Analytical Procedures

The registration application should include documented evidence that the analytical procedures are validated and suitable for the detection and quantitation of impurities (see ICH Q2A and Q2B guidances for analytical validation). Differences in the analytical procedures used during development and those proposed for the commercial product should be discussed in the registration application.

Organic impurity levels can be measured by a variety of techniques, including those which compare an analytical response for an impurity to that of an appropriate reference standard or to the response of the new drug substance itself. Reference standards used in the analytical procedures for control of impurities should be evaluated and characterized according to their intended uses. It is considered acceptable to use the drug substance as a standard to estimate the levels of impurities. In cases where the response factors are not close, this practice may still be acceptable, provided a correction factor is applied or the impurities are, in fact, being overestimated. Specifications and analytical procedures used to estimate identified or unidentified impurities are often based on analytical assumptions (e.g., equivalent detector response). These assumptions should be discussed in the registration application.

5. Reporting Impurity Content of Batches

Analytical results should be provided for all batches of the new drug substance used for clinical, safety, and stability testing, as well as for batches representative of the proposed commercial process. The content of individual identified and unidentified and total impurities observed in these batches of the new drug substance should be reported with the analytical procedures indicated. A tabulation (e.g., spreadsheet) of the data is recommended. Impurities should be designated by code number or by an appropriate descriptor, e.g., retention time. Levels of impurities that are not more than (>) the reporting threshold given in Attachment 1 need not be reported. A higher reporting threshold should only be proposed with justification. All impurities at a level greater than (>) the reporting threshold should be summed and reported as Total Impurities. The summation should be performed on the unrounded individual values, and the total value should be rounded and reported as described in section 3.1. When analytical procedures change during development, reported results should be linked to the procedure used, with appropriate validation information provided. Representative chromatograms should be provided. Chromatograms of such representative batches from methods validation studies showing separation and detectability of impurities (e.g., on spiked samples), along with any other impurity tests routinely performed, can serve as the representative impurity profiles. The applicant should ensure that complete impurity profiles (i.e., chromatograms) of individual batches are available if requested.

A tabulation should be provided that links the specific new drug substance batch to each safety study and each clinical study in which it has been used.

For each batch of the new drug substance, the report should include:

- Batch Identity and Size
- Date of Manufacture
- Site of Manufacture
- Manufacturing Process
- Impurity Content, Individual and Total
- Use of Batches
- Reference to Analytical Procedure Used

6. Specifications for Impurities

The specifications for a new drug substance should include limits for impurities. Stability studies, chemical development studies, and routine batch analyses can be used to predict those impurities likely to occur in the commercial product. The selection of impurities to include in the new drug substance specifications should be based on the impurities found in batches manufactured by the proposed commercial process. Those impurities selected for inclusion in the specifications for the new drug substance are referred to as ''specified impurities'' in this guidance. Specified impurities may be identified or unidentified and should be individually listed in the new drug substance specifications.

A rationale for the inclusion or exclusion of impurities in the specifications should be presented. This rationale should include a discussion of the impurity profiles observed in the safety and clinical development batches, together with a consideration of the impurity profile of material manufactured by the proposed commercial process. Specific identified impurities should be included along with specified unidentified impurities estimated to be present at a level greater than (>) the qualification/identification threshold given in Attachment 1. For impurities known to be unusually potent or to produce toxic or unexpected pharmacological effects, the quantitation/detection limit of the analytical methods should be commensurate with the level at which the impurities must be controlled. For unidentified impurities, the procedure used and assumptions made in establishing the level of the impurity should be clearly stated. Specified unidentified impurities included in the specifications should be referred to by an appropriate qualitative analytical descriptive label (e.g., ''unidentified A,'' ''unidentified with relative retention of 0.9''). Finally, a general specification limit of not more than (≤) the qualification/identification threshold (Attachment 1) for any unspecified impurity should be included.

Limits should be set no higher than the level that can be justified by safety data and consistent with the level achievable by the manufacturing process and the analytical capability. Where there is no safety concern, impurity specifications should be based on data generated on batches of the new drug substance manufactured by the proposed commercial process, allowing sufficient latitude to deal with normal manufacturing and analytical variation, and the stability characteristics of the new drug substance. Although normal manufacturing variations are expected, significant variation in batch-to-batch impurity levels may indicate that the manufacturing process of the new drug substance is not adequately controlled and validated (see ICH Q6A guidance on specifications).

In summary, the new drug substance specifications should include, where applicable, limits for:

Organic Impurities

- Each Specified Identified Impurity
- Each Specified Unidentified Impurity at a level greater than (>) the qualification/identification threshold
- Any Unspecified Impurity with a limit of not more than (≤) the qualification/identification threshold
- Total Impurities

Residual Solvents

Inorganic Impurities

7. Qualification of Impurities

Qualification is the process of acquiring and evaluating data that establishes the biological safety of an individual impurity or a given impurity profile at the level(s) specified. The applicant should provide a rationale for selecting impurity limits based on safety considerations. The level of any impurity present in a new drug substance that has been adequately tested in safety and/or clinical studies is considered qualified. Impurities that are also significant metabolites present in animal and/or human studies do not need further qualification. A level of a qualified impurity higher than that present in a new drug substance can also be justified based on an analysis of the actual amount of impurity administered in previous relevant safety studies.

If data are not available to qualify the proposed specification level of an impurity, studies to obtain such data may be needed when the usual qualification threshold limits given in Attachment 1 are exceeded.

Higher or lower threshold limits for qualification of impurities may be appropriate for some individual drugs based on scientific rationale and level of concern, including drug class effects and clinical experience. For example, qualification may be especially important when there is evidence that such impurities in certain drugs or therapeutic classes have previously been associated with adverse reactions in patients. In these instances, a lower qualification threshold limit may be appropriate. Conversely, a higher qualification threshold limit may be appropriate for individual drugs when the level of concern for safety is less than usual based on similar considerations (e.g., patient population, drug class effects, clinical considerations). Technical factors (manufacturing capability and control

methodology) may be considered as part of the justification for selection of alternative threshold limits based on manufacturing experience with the proposed commercial process. Proposals for alternative threshold limits are considered on a case-by-case basis.

The ''Decision Tree for Safety Studies'' (Attachment 2) describes considerations for the qualification of impurities when thresholds are exceeded. In some cases, decreasing the level of impurity below the threshold may be simpler than providing safety data. Alternatively, adequate data may be available in the scientific literature to qualify an impurity. If neither is the case, additional safety testing should be considered. The studies desired to qualify an impurity will depend on a number of factors, including the patient population, daily dose, and route and duration of drug administration. Such studies are normally conducted on the new drug substance containing the impurities to be controlled, although studies using isolated impurities are acceptable.

8. New Impurities

During the course of a drug development program, the qualitative impurity profile of the new drug substance may change, or a new impurity may appear as a result of synthetic route changes, process optimization, scale-up, etc. New impurities may be identified or unidentified. Such changes call for qualification of the level of the impurity unless it is not more than (>) the threshold values as noted in Attachment 1. When a new impurity exceeds the threshold, the ''Decision Tree for Safety Studies'' should be consulted. Safety studies should compare the new drug substance containing a representative level of the new impurity with previously qualified material, although studies using the isolated impurity are also acceptable (these studies may not always have clinical relevance).

9. Glossary

Chemical development studies: Studies conducted to scale-up, optimize, and validate the manufacturing process for a new drug substance.

Enantiomers: Compounds with the same molecular formula as the drug substance, which differ in the spatial arrangement of atoms within the molecule and are nonsuperimposable mirror images.

Extraneous substance: An impurity arising from any source extraneous to the manufacturing process.

Herbal products: Medicinal products containing, exclusively, plant material and/or vegetable drug preparations as active ingredients. In some traditions, materials of inorganic or animal origin may also be present.

Identification threshold: A limit above which (>) an impurity needs identification.

Identified impurity: An impurity for which a structural characterization has been achieved.

Impurity: Any component of the new drug substance that is not the chemical entity defined as the new drug substance.

Impurity profile: A description of the identified and unidentified impurities present in a new drug substance.

Intermediate: A material produced during steps of the synthesis of a new drug substance that must undergo further molecular change before it becomes a new drug substance.

Ligand: An agent with a strong affinity to a metal ion.

New drug substance: The designated therapeutic moiety that has not been previously registered in a region or member State (also referred to as a new molecular entity or new chemical entity). It may be a complex, simple ester, or salt of a previously approved drug substance.

Polymorphism: The occurrence of different crystalline forms of the same drug substance.

Potential impurity: An impurity that, from theoretical considerations, may arise from or during manufacture. It may or may not actually appear in the new drug substance.

Qualification: The process of acquiring and evaluating data that establishes the biological safety of an individual impurity or a given impurity profile at the level(s) specified.

Qualification threshold: A limit above which (>) an impurity needs to be qualified.

Reagent: A substance, other than a starting material or solvent, that is used in the manufacture of a new drug substance.

Reporting threshold: A limit above which (>) an impurity needs to be reported.

Rounding: The process of reducing a result to the number of significant figures or number of decimal places as dictated by the appropriate limit. For example, a result greater than or equal to (≥) 0.05 and less than (<) 0.15 is rounded to 0.1.

Safety information: The body of information that establishes the biological safety of an individual impurity or a given impurity profile at the level(s) specified.

Solvent: An inorganic or an organic liquid used as a vehicle for the preparation of solutions or suspensions in the synthesis of a new drug substance.

Specified impurity: Identified or unidentified impurity that is selected for inclusion in the new drug substance specifications and is individually listed and limited in order to ensure the safety and quality of the new drug substance.

Starting material: A material used in the synthesis of a new drug substance that is incorporated as an element into the structure of an intermediate and/or of the new drug substance. Starting materials are normally commercially available and of defined chemical and physical properties and structure.

Toxic impurity: An impurity having significant undesirable biological activity.

Unidentified impurity: An impurity that is defined solely by qualitative analytical properties (e.g., chromatographic retention time).

Unspecified impurity: An impurity that is not included in the list of specified impurities.

ATTACHMENT 1

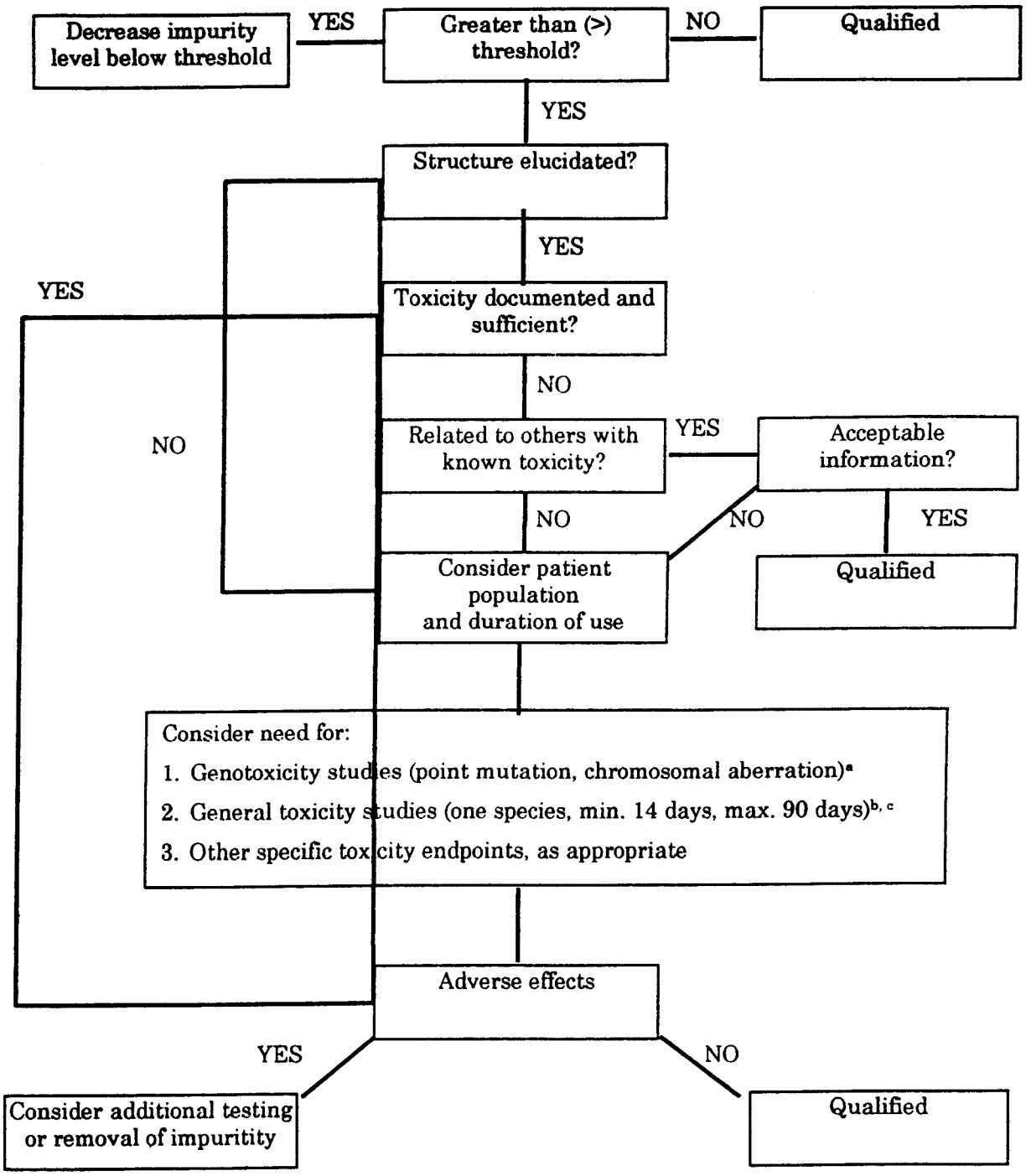
Maximum Daily Dose	Qualification Threshold and Identification Threshold	Reporting Threshold [1]
≤ 2 grams (g)/day	0.1 percent or 1 milligram per day intake (whichever is lower)	0.05 percent
> 2 g/day	0.05 percent	0.03 percent

[1] Higher reporting thresholds should be scientifically justified.

BILLING CODE 4160–01–F

ATTACHMENT 2

DECISION TREE FOR SAFETY STUDIES



Notes on Attachment 2

[a] If considered desirable, a minimum screen for genotoxic potential should be conducted. A study to detect point mutations and one to detect chromosomal aberrations, both in vitro, are recommended as an acceptable minimum screen.

[b] If general toxicity studies are desirable, study(ies) should be designed to allow comparison of unqualified to qualified material. The study duration should be based on available relevant information and performed in the species most likely to maximize the potential to detect the toxicity of an impurity. In general, a minimum duration of 14 days and a maximum duration of 90 days are recommended.

[c] On a case-by-case basis, single-dose studies may be acceptable, especially for single-dose drugs. If repeat-dose studies are desirable, a maximum duration of 90 days would be acceptable.

Dated: July 10, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–18151 Filed 7–19–00; 8:45 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–264 A–H]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Medicare DMEPOS Competitive Bidding Demonstration;

Form No.: HCFA–R–264 A–H (OMB #0938–0748);

Use: Section 1847 of the Social Security Act, as added by Section 4319 of the Balanced Budget Act (BBA), mandates HCFA to implement demonstration projects under which competitive acquisition areas are established for contract award purposes for the furnishing of Part B items and services, except for physician's services. The demonstration currently operating in Polk County, Florida and the demonstration planned for San Antonio, Texas involve competitive bidding of categories of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The new set of products to be offered for competitive bidding in San Antonio are: Oxygen equipment and supplies, hospital beds, non-customized orthotic devices, manual wheelchairs and accessories, and nebulizer inhalation drugs. Under the law, suppliers can receive payments from Medicare for items and services covered by the demonstration only if their bids are competitive in terms of quality and price. Each demonstration project may be conducted in up to three metropolitan areas for a three year period. Authority for the demonstration expires on December 31, 2002.

There are eight forms that are required for this demonstration. Form A will be used by the bidding supplier to provide information about the characteristics of the company. Form B will be used by the bidding supplier to provide specific information about the prices it bids for specific product categories, and to provide information about the attributes of the supplier in relation to the specific product category. Form C will be used by HCFA or its agents to obtain information on site regarding the bidding supplier. Form D will be used by HCFA or its agents to obtain financial references on the bidding supplier from banks and other financial sources. Form E will be used by HCFA or its agents to obtain information about the bidding suppliers from referral sources such as home health agencies and hospital discharge planners. Form F will be used to obtain information about the suppliers' financial status and to assure that they have sufficient fiscal resources to operate in a competitive environment where the prices being paid for some products are less than what have been customarily paid. It is required only from suppliers whose bids are in the competitive range. Form G will be used for nursing homes to identify their suppliers of products and services who have not been awarded Demonstration Supplier status for services to beneficiaries in their home. This is to permit payment to those suppliers for products and services furnished to nursing homes. Form H will be used to monitor the performance of Demonstration Suppliers to assure their adherence to the quality standards established for the project.

The competitive bidding demonstration for DMEPOS has the following objectives:

- Test the policies and implementation methods of competitive bidding to determine whether or not it should be expanded as a Medicare Program.
- Reduce the price that Medicare pays for medical equipment and supplies.
- Limit beneficiary out-of-pocket expenditures for copayments.
- Assure beneficiary access to high quality medical equipment and supplies.
- Prevent business transactions with suppliers who engage in fraudulent practices.

Frequency: On occasion;

Affected Public: Business or other for-profit, and not-for-profit institutions;

Number of Respondents: 5,100;

Total Annual Responses: 1,700;

Total Annual Hours: 12,420.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 11, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–18378 Filed 7–19–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–684A–I and HCFA–685]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this