DATES: Submit written or electronic comments on the collection of information by April 14, 2003.

ADDRESSES: Submit electronic comments on the collection of information to: *barbara.lewis@aoa.gov.* Submit written comments on the collection of information to Administration on Aging, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Barbara Lewis, Administration on Aging, Center for Wellness and Community-Based Services, Office of Consumer Choice and Protection, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

This information collection, Senior Medicare Patrol Projects, continues an existing collection, which had been administered by the Office of Inspector General (OIG) to prevent error, fraud and abuse in the Medicare Program. This is now being transferred from the OIG to the Administration on Aging, and administered under Title IV of the Older Americans Act.

Grantees are required by Congress to provide information for use in program monitoring and for GPRA purposes. This information collection reports the number of new trainers trained and other Medicare outreach activities, and the number of dollars recouped for the Medicare Trust Fund.

AoA estimates the burden of this collection of information as follows: a total of 8 hours for each of 51 grantees per year for the two semi-annual reports.

Dated: February 4, 2003.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. 03–3326 Filed 2–10–03; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94D–0325]

International Conference on Harmonisation; Revised Guidance on Q3A Impurities in New Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance entitled ''Q3A(R) Impurities in New Drug Substances.'' The 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 revised guidance clarifies the 1996 guidance, adds information, and provides consistency with more recently published ICH guidances. The 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: The guidance is effective February 11, 2003. Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 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. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORAMTION** section of this document for electronic access to the guidance.

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, 301–827–5918.

Regarding the ICH: Janet Showalter, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

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, Labour, and Welfare, and 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, Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is now being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedure for publishing ICH guidances. As of April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance is placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). Draft guidances are left in the original ICH format. The final guidance is reformatted to conform to the GGP style before publication.

In the **Federal Register** of July 20, 2000 (65 FR 45085), FDA published a draft revised tripartite guidance entitled ''Q3A(R) Impurities in New Drug Substances.'' The notice gave interested persons an opportunity to submit comments by September 18, 2000. The draft revised guidance was a revision of ICH guidance on the same topic published in the **Federal Register** of January 4, 1996 (61 FR 372).

After consideration of the comments received and revisions to the guidance by the Quality Expert Working Group of the ICH, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on February 6, 2002.

ICH Q3A(R) provides guidance on the information for drug marketing registration regarding the content and qualification of impurities in new drug substances produced by chemical syntheses and not previously registered within the three regions of the EC, Japan, and the United States. The guidance is not intended to apply to new drug substances used during the clinical research stage of development. The following types of drug substances are not covered in this guidance: Biological/biotechnological, peptide, oligonucleotide, radiopharmaceutical, fermentation products and semisynthetic products derived therefrom, herbal products, and crude products of animal or plant origin.

Impurities in new drug substances are addressed in the guidance from two different perspectives: (1) Chemistry aspects—classification and identification of impurities in specifications, report generation, listing of impurities in specifications, and a brief discussion of analytical procedures; and (2) safety aspects—guidance for qualifying those impurities that were not present, or were present at substantially lower levels, in batches of the new drug substance used in safety and clinical studies.

The ICH Q3A guidance was revised to add information to certain sections and to provide clarification to other sections of the previous guidance. The most important sections that have been revised are:

- The text on reporting, identification, and qualification thresholds.
- The text on listing impurities in specifications to provide a clear distinction between ICH Q3A (listing impurities) and ICH Q6A (setting specifications).
- The deletion of the exception to conventional rounding practice, i.e., the provision recommending no rounding up to 0.1 percent for values between 0.05 and 0.03 percent.
- Attachment 2—an illustration of reporting impurity results for identification and qualification in an application.
- Attachment 3—a decision tree for identification and qualification.
- Additions and revisions to the previous glossary include definitions for the terms ''unspecified impurity,'' ''identification threshold,'' and ''qualification threshold.''
- References to more recently published ICH guidances entitled ''Q3B(R) Impurities in New Drug Products,'' ''Q3C Impurities: Residual Solvents,'' and ''Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances.''

Minor editorial changes were made to improve the clarity and consistency of the document.

This 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 statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any mailed 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. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/publications.htm, or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: February 4, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–3352 Filed 2–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0002]

Medical Devices; Export Certificates; FDA Export Reform and Enhancement Act of 1996; Certification Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the new fees the agency will assess for issuing export certificates for devices. The FDA Export Reform and Enhancement Act of 1996 (EREA) provides that any person who exports a device may request that FDA certify in writing that the exported device meets certain specified requirements. It further provides that FDA shall issue such a certification within 20 days of the receipt of a request for such certification and that FDA may charge up to $175 for each certification that is issued within