

**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](mailto: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.*

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## 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 INFORMATION** 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