meeting. Preregistration is required for public comment. Any individual who wishes to participate in the public comment session should call the telephone number listed in the contact information to register. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed material distributed to CFSAC members should submit materials to the Executive Secretary, CFSAC, whose contact information is listed above prior to close of business December 1, 2003.

Dated: November 7, 2003.

Larry E. Fields,

Executive Secretary, Chronic Fatigue Syndrome Advisory Committee.

[FR Doc. 03–28579 Filed 11–13–03; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1996D–0009]

International Conference on Harmonisation; Revised Guidance on Q3B(R) Impurities in New Drug Products; 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 ''Q3B(R) Impurities in New Drug Products.'' The revised guidance, which updates a guidance on the same topic published in the **Federal Register** of May 19, 1997 (the 1997 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 is intended to provide guidance to applicants for drug marketing registration on the content and qualification of impurities in new drug products produced by chemically synthesized new drug substances not previously registered in a country, region, or member State. The revised guidance clarifies the 1997 guidance, adds information, and provides consistency with more recently published ICH guidances. The revised guidance complements the ICH guidance entitled ''Q3A(R) Impurities in New Drug Substances.''

DATES: The guidance is effective November 14, 2003. Submit written or electronic comments at any time.

ADDRESSES: Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. 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 20852–1448, 301–827–3844, FAX: 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your request. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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; or

Andrew Shrake, Center for Biologics Evaluation and Research (HFM–345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20052–1148, 301–402–4635.

Regarding the ICH: Michelle Limoli, 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, the Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In the **Federal Register** of February 11, 2003 (68 FR 6924), the agency published an ICH guidance entitled ''Q3A(R) Impurities in New Drug Substances,'' which revised Q3A. The guidance Q3A(R) provides recommendations to applicants for drug marketing registration on the content and qualification of impurities in new drug substances produced by chemical synthesis and not previously registered in a country, region, or member state.

In the **Federal Register** of July 19, 2000 (65 FR 44791), FDA published a draft tripartite guidance entitled ''Q3B(R) Impurities in New Drug Products.'' The notice gave interested persons an opportunity to submit comments by September 18, 2000.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee; the three participating regulatory agencies endorsed it in February 2003.

This revised guidance complements the ICH Q3A(R) guidance and provides recommendations for registration or marketing applications on the content and qualification of impurities in new drug products produced from chemically synthesized new drug substances not previously registered in a region or member state. The revised guidance addresses only those impurities in new drug products

classified as degradation products of the drug substance or reaction products of the drug substance with an excipient and/or immediate container closure system. Impurities arising from excipients present in the new drug product or extracted or leached from the container closure system are not addressed in this revised guidance.

The Q3B(R) guidance has been 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 the listing of impurities in specifications and a clear distinction between ICH Q3B (listing impurities) and 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 0.09 percent.
- Attachment 2—an illustration of reporting degradation product results for identification and qualification in an application.
- Attachment 3—a decision tree for identification and qualification of a degradation product.
- Additions and revisions to the previous glossary including definitions for the terms ''unspecified degradation product,'' ''reporting threshold,'' ''identification threshold,'' and ''qualification threshold.''
- References to more recently published ICH guidances (e.g., ''Q3A(R) Impurities in New Drug Substances,'' Q3C Impurities: Residual Solvents,'' and ''Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances'').

In addition, minor editorial changes were made to improve the clarity and consistency of the document.

This guidance represents the agency's current thinking on this topic. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any mailed comments are to be submitted, except 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 are available for public examination in the Division of Dockets Management 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/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: November 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy

[FR Doc. 03–28457 Filed 11–13–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Customer Satisfaction With Educational Programs and Products of the National Cancer Institute

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on May 29, 2003, page 32067 and allowed 60 days for public comment. Comments were received from two individuals, both of whom are contractors interested in the potential for conducting portions of the proposed information collection activities. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Customer Satisfaction with Educational Programs and Products of the National Cancer Institute. *Type of Information Collection Request:* NEW. *Need and Use of the Information Collection:* The Office of Education and Special Initiatives (OESI) of the National Cancer Institute (NCI) is responsible for the design, implementation, and evaluation of education programs over the entire cancer continuum, including prevention, screening, diagnosis, treatment, survivorship, and palliative care; it also manages NCI initiatives that address specific challenges in cancer research and treatment. To help ensure the relevance, utility, and appropriateness of the many educational programs and products that OESI and NCI produce, OESI intends to collect information on customer satisfaction with those products through customer satisfaction surveys. By obtaining information from customers on the extent to which materials satisfy their needs, OESI and NCI will be able to systematically establish and follow a feedback loop that provides useful information to revise and enhance educational programs and products so that they attain maximum relevance, utility, appropriateness, and impact. Data will be collected through various means, including telephone, mail, in-person, and web-based surveys. *Frequency of Response:* On occasion. *Affected Public:* individuals or households, organizations involved in providing health care services. *Type of Respondents:* health care consumers of NCI educational programs or products, including cancer patients and families, health care professionals, cancer control planners, and policymakers. The estimated annual burden hours are as follows: *Estimated Number of Respondents:* 2547; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .167; and *Estimated Total Annual Burden Hours Requested:* 910 (425???). The annualized cost to respondents is estimated at: $17,049. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological