estimates for these information collection requirements are based on information provided by the Office of New Animal Drug Evaluation, Center for Veterinary Medicine. The guidance document describes the type of information that should be collected by the drug sponsor when completing the antimicrobial resistance risk assessment. FDA will use the risk assessment and supporting information to evaluate the safety of original (21 CFR 514.1) or supplemental (21 CFR 514.8) NADAs for antimicrobial drugs intended for use in food-producing animals.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Antimicrobial Risk Assessments	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
Hazard Identification (initial scoping of issues; relevant bacteria, resistance determinants, food products; preliminary data gathering)	15	1	15	30	450
Release Assessment (literature review; review of research reports; data development; compilation, and presentation)	10	1	10	1,000	10,000
Exposure Assessment (identifying and extracting consumption data; estimating probability of contamination on food product)	10	1	10	8	80
Consequence Assessment (review ranking of human drug importance table)	10	1	10	4	40
Risk Estimation (integration of risk components; development of potential arguments as basis for overall risk estimate)	10	1	10	12	120
Risk Management (discussion of appropriate risk management activities)	10	1	10	30	300
Total Burden					10,990

[1]There are no capital costs and operating and maintenance costs associated with this collection of information.

FDA estimates that on an annual basis an average of 15 NADAs (including original applications and major supplements) would be subject to information collection under this guidance. This estimate is based on the number of reviews completed between October 2003 and October 2004. During that period, microbial food safety for approximately 15 antimicrobial NADAs (including original and major supplements) was evaluated. This estimate excludes NADAs for antimicrobial drug combinations, generic drug applications (ANADAs), and certain supplemental NADAs.

Dated: June 23, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12910 Filed 6–29–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001N–0275 (formerly Docket No. 01N–0275)]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Performance Standard for Diagnostic X-Ray Systems and Their Major Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Performance Standard for Diagnostic X-Ray Systems and Their Major Components'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 2005 (70 FR 33998 at 34012), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0564. The approval expires on December 31, 2006. A copy of the supporting statement for

this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 23, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12911 Filed 6–29–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0118]

International Conference on Harmonisation; Guidance on Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The purpose of the guidance is to provide principles for assessing the comparability of biotechnological/biological products before and after changes are made in the manufacturing process for the drug substance or drug product. The guidance is intended to assist in the collection of relevant technical information that serves as evidence that the manufacturing process changes will not have an adverse impact on the quality, safety, and efficacy of the drug product.

DATES: Submit written or electronic comments on agency guidances 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. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Barry Cherney, Center for Drug Evaluation and Research (HFD–122), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–1790; or Andrew Chang, Center for Biologics Evaluation and Research (HFM–340), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–496–4833.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

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; 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, and the European Free Trade Area.

In the **Federal Register** of March 30, 2004 (69 FR 16580), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process.'' The notice gave interested persons an opportunity to submit comments by May 19, 2004.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2004.

The document provides guidance on the principles for assessing the comparability of biotechnological/biological products before and after changes are made in the manufacturing process for the drug substance or drug product. The document does not prescribe any particular analytical, nonclinical, or clinical strategy. The main focus of the document is on quality aspects.

This guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The guidance represents the agency's current thinking on Q5E comparability of biotechnological/biological products subject to changes in their manufacturing process. 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.

Note that FDA may have existing guidance on this or related topics, such as ''FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products,'' available at *http://www.fda.gov/cber/gdlns/comptest.txt*.