fiscal years (953), multiplied by the conservative frequency of reporting per year (13).

D. Termination of a Recall

Provide the firms an opportunity to request in writing that FDA end the recall. The Agency estimates it will receive 953 responses annually based on the average number of terminations over the past 3 fiscal years.

II. Hours per Response Estimates

FDA has no information which would allow it to make a calculated estimate on the hours per response burden to FDA regulated firms to conduct recalls. Variables in the type of products, the quantity and level of distribution and the various circumstances of recall notifications could cause the hours per response to vary significantly. The best guesstimate of average burden hours per response from previous information collection request reports are utilized again for the current estimates on burden hours per response.

Dated: June 23, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–16252 Filed 6–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0502]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; National Consumer Surveys on Understanding the Risks and Benefits of FDA—Regulated Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 29, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''National Consumer Surveys on Understanding the Risks and Benefits of FDA–Regulated Medical Products.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794.

JonnaLynn.Capezzuto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

National Consumer Surveys on Understanding the Risks and Benefits of FDA–Regulated Medical Products—(OMB Control Number 0910–NEW)

Risks and benefits are inherent in all FDA-regulated medical products, including drugs, biologics, and medical devices (*e.g.,* pacemakers, implantable cardiac defibrillators, contact lenses, infusion pumps). FDA plays a critical oversight role in managing and preventing injuries and deaths related to medical product use. However, the users of FDA-regulated products are ultimately the ones who determine which products are used and how they are potentially misused. For this reason, it is critical that the public understand the risks and benefits of FDA-regulated medical products to a degree that allows them to make rational decisions about product use.

FDA's responsibility includes communicating about medical products. This encompasses communications that FDA generates and those it oversees through regulation of product manufacturers' and distributors' communications. Activities include, but are not limited to, recall notices, warnings, public health advisories and notifications, press releases, and information made available on its Web site. FDA also regulates communications drafted and disseminated by manufacturers and distributors of many medical products, including all the communications (advertising and labeling) about prescription drugs, biologics, and restricted medical devices, and a subset of communications (omitting advertising) about nonprescription drugs and other medical devices. In order to conduct educational and public information programs relating to these responsibilities, as authorized by section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), it is beneficial for FDA to conduct research and studies relating to health information as authorized by section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)).

In conducting such research, FDA will employ nationally representative surveys of consumers to assess whether the information being disseminated by both the Agency and the entities it regulates is appropriately reaching targeted audiences in an understandable fashion. Specifically, the surveys will assess public understanding about the benefits and risks of medical products and FDA's role in regulating these products. The surveys will assess behaviors and beliefs related to the use of medical products, when consumers desire emerging risk information, the likelihood of reporting serious side effects that might be associated with medical product use, perceptions of the credibility of FDA and other potential sources of risk and benefit information, and satisfaction with FDA's communications-related performance.

Parallel surveys of 1,500 noninstitutionalized U.S. adults will be administered. One survey of 1,500 subjects will be a telephone survey, and the second survey of another 1,500 subjects will be conducted with members from an Internet panel. Both survey samples will be constructed to be representative of the U.S. population, and both will take approximately 15 minutes to administer. Results from each survey will be compared to provide insight into the best methodology for future studies.

The information collected will be used by FDA in the development of more effective risk communication strategies and messages. The surveys will provide FDA insight as to how well the public understands and incorporates risk/benefit information into their belief structures, and how well the public understands the context within which FDA makes decisions on medical product recalls and warnings. Using this information, the Agency will more effectively design messages and select formats and distribution channels that have the greatest potential to influence the target audience's attitudes and behavior in a favorable way. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; *Type of Respondents:* Members of the public.

In the **Federal Register** of October 5, 2010 (75 FR 61490), FDA published a 60-day notice requesting public comment on the proposed collection of

information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretests	30	1	30	0.25 (15 min.)	8
Screener	6,700	1	6,700	0.10 (6 min.)	670
Telephone survey	1,500	1	1,500	0.25 (15 min.)	375
Internet panel survey	1,500	1	1,500	0.25 (15 min.)	375
Total					1,428

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

Dated: June 23, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–16251 Filed 6–28–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0436]

International Conference on Harmonisation; Draft Guidance on Q11 Development and Manufacture of Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Q11 Development and Manufacture of Drug Substances.'' The draft 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 guidance describes approaches to developing process and drug substance understanding and provides guidance on what information should be provided in certain sections of the Common Technical Document (CTD). The draft guidance is intended to harmonize the scientific and technical principles relating to the description and justification of the development and manufacturing process of drug substances (both chemical entities and biotechnological/biological entities) to enable a consistent approach for providing and evaluating this information across the three regions.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 1, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the Guidance

John Smith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 2619, Silver Spring, MD 20993–0002, 301–796–1757; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0373.

Regarding the ICH

Michelle Limoli, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 3506, Silver Spring, MD 20993–0002, 301–796–4600.

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