including economic and technical considerations and agency statutory missions. GSA shall identify and discuss all such factors including any essential considerations of national policy which is balanced by GSA in making its decision and state how those considerations entered into its decision.

Supplemental Information:

GSA invites interested individuals, organizations, and federal, state, and local agencies to participate in defining and identifying any significant impacts and issues to be studied in the EIS. The EIS will examine the short and long-term impacts on the natural and physical environment. The assessment will include but not be limited to impacts such as social environment, changes in land use, aesthetics, changes in adjacent park land, changes in traffic patterns and access to the ''D'' street intersection, economic impacts, and consideration of City planning and zoning requirements. The EIS will examine measures to mitigate significant adverse impacts resulting from the proposed action. Concurrent with NEPA implementation, GSA will also implement its consultation responsibilities under Section 106 of the National Historic Preservation Act to identify potential impacts to existing historic or cultural resources. GSA will consult with Native American tribes through-out the NEPA process.

The EIS will consider a no-action alternative and action alternatives. The no-action alternative would continue the occupancy in the existing Peace Arch Port of Entry facility in Blaine. The action alternatives will consist of three different configurations for construction of a new port of Entry facility.

Dated: 11/18/2005.

William L. DuBray,

Executive Director, Region 10.

[FR Doc. 05–23522 Filed 11–30–05; 8:45 am]

BILLING CODE 6820–EP–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0335]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority

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 January 3, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

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

Medical Device Recall Authority—21 CFR Part 810 (OMB Control Number 0910–0432)—Extension

This collection implements medical device recall authority provisions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) and part 810 (21 CFR part 810). Section 518(e) of the act gives FDA the authority to issue an order requiring the appropriate person, including manufacturers, importers, distributors, and retailers of a device, to immediately cease distribution of such device, to immediately notify health professionals and device-user facilities of the order, and to instruct such professionals and facilities to cease use of such device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death.

Section 518(e) of the act sets out a three-step procedure for issuance of a mandatory device recall order. First, if there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately do the following: (1) Cease distribution of the device, (2) notify health professionals and device user facilities of the order, and (3) instruct those professionals and facilities to cease use of the device. Second, FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device. Third, after providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the agency determines that such an order is necessary.

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to accurately and immediately detect serious problems with medical devices, and to remove dangerous and defective devices from the market.

The respondents to this proposed collection of information are manufacturers, importers, distributors, and retailers of medical devices.

In the **Federal Register** of September 2, 2005 (70 FR 52397), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a) through (b)	1	1	1	8	8

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.14	2	1	2	16	32
810.15(a) through (d)	2	1	2	16	32
810.15(e)	10	1	10	1	10
810.16	2	12	24	40	960
810.17	2	1	2	8	16
Total					1,082

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

The following burden estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily.

Section 810.10(d)—FDA estimates that it will take approximately 8 hours for the person named in a cease distribution and notification order to gather and submit the information required by this section.

The total estimated annual burden is 16 hours.

Section 810.11(a)—Based on experience in similar situations, FDA expects that there will be only one request for a regulatory hearing per year and that it will take approximately 8 hours to prepare this request.

Section 810.12(a) and (b)—Based on experience in similar situations, FDA expects that there will be only one written request for a review of a cease distribution and notification order per year and that it will take approximately 8 hours to prepare this request.

Section 810.14—Based upon its experience with voluntary recalls, FDA estimates that it will take approximately 16 hours to develop a strategy for complying with the order.

Section 810.15(a) through (d)—Based upon its experience with voluntary recalls, FDA estimates that it will take approximately 16 hours to notify each health professional, user facility, or individual of the order.

Section 810.15(e)—Based upon its experience with voluntary recalls, FDA estimates that there will be approximately five consignees per recall (10 per year) who will be required to notify their consignees of the order. FDA estimates that it will take them about 1 hour to do so.

Section 810.16—FDA estimates that it would take no more than 40 hours to assemble and prepare a written status report required by a recall. The status reports are prepared by manufacturers six to twelve times each year. Therefore, each manufacturer would spend no more than 480 hours each year preparing status reports. If there were two FDA invoked recalls each year, the total burden hours estimated would be 960 hours each year.

Section 810.17—Based on experience with similar procedures, FDA estimates that it would take 8 hours to draft a written request for termination of a cease distribution and notification or mandatory recall order.

Dated: November 23, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23519 Filed 11–30–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0438]

Draft Guidance for Industry on Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency,'' dated November 2005. The draft guidance document provides recommendations for testing the safety, efficacy, and pharmacokinetics of immune globulin intravenous (human) (IGIV) products as replacement therapy in primary humoral immunodeficiency. The draft guidance document is intended to assist sponsors with the design of clinical trials to assess IGIV as replacement therapy in primary humoral immunodeficiency.

DATES: Submit written or electronic comments on the draft guidance by March 1, 2006, to ensure their adequate consideration in the preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 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 the Center for Biologics Evaluation and Research at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft 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*.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for