contains no more than 25 micrograms per liter (µg/L). This information must be contained in the ''Precautions'' section of the labeling of all LVPs used in TPN therapy.

21 CFR 201.323(c)—Requires that the maximum level of aluminum present at expiry be stated on the immediate container label of all SVP drug products and PBPs used in the preparation of TPN solutions. The aluminum content must be stated as prescribed in the regulation. The immediate container label of all SVP drug products and PBPs that are lyophilized powders used in the preparation of TPN solutions must contain the statement prescribed in the regulation.

21 CFR 201.323(d)—Requires that the package insert for all LVPs, SVPs, and PBPs used in TPN contain a warning statement, prescribed in the regulation, intended for patients with impaired kidney function and for neonates receiving TPN therapy. This information must be contained in the ''Warnings'' section of the labeling.

21 CFR 201.323(e)—Requires that applicants and manufacturers must use validated assay methods to determine the aluminum content in parenteral drug products. The assay methods must comply with current good manufacturing practice requirements. Applicants must submit to FDA both validation of the method used and release data for several batches. Manufacturers of parenteral drug products not subject to an approved application must make assay methodology available to FDA during inspections. Holders of pending applications must submit an amendment to the application.

Compliance with the information collection burdens under §201.323(b), (c), and (d) (21 CFR 201.323(b), (c), and (d)) consists of submitting application supplements to FDA containing the revised labeling for each product. Based on data concerning the number of applications for LVPs, SVPs, and PBPs used in TPN received by the agency, FDA estimates that the labeling for approximately 200 products will be changed under §201.323(b), (c), and (d). FDA estimates that it will take approximately 14 hours to prepare and submit to FDA each labeling change. FDA estimates that approximately 65 respondents will each submit 1 validated assay method annually under §201.323(e). FDA estimates that it will take approximately 14 hours to prepare and submit to FDA each validated assay.

In the **Federal Register** of December 19, 2002 (67 FR 77792), the agency requested comments on the proposed collection of information. No comments were received.

The burdens can be charted 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
201.323(b),(c),(d)	200	1	200	14	2,800
201.323(e)	65	1	65	14	910
Total					3,710

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

Dated: March 10, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–6227 Filed 3–14–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0085]

Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in FDA regulations entitled ''Environmental Impact Considerations.''

DATES: Submit written or electric comments on the collection of information by May 16, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm*. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 requests 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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.

Environmental Impact Considerations—21 CFR Part 25 (OMB Control Number 0910–0322)—Extension

FDA is requesting OMB approval for the reporting requirements contained in the FDA regulation entitled ''Environmental Impact Considerations.''

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4347), states national environmental objectives and imposes upon each Federal agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

FDA's NEPA regulations are at part 25 (21 CFR part 25). All applications or petitions requesting agency action require the submission of a claim for a categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

This collection of information is used by FDA to assess the environmental impact of agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse effects cannot be avoided, the agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency. The final EIS including the comments received is reviewed by the agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact. Any final EIS would contain additional information gathered by the agency after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and the agency's responses to the comments, including any revisions resulting from the comments or other information. When the agency finds that no significant environmental effects are expected, the agency prepares a finding of no significant impact.

Estimated Annual Reporting Burden for Human Drugs

Under 21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 2002, FDA received 2,374 INDs from 1,809 sponsors, 109 NDAs from 79 applicants, 2,575 supplements to NDAs from 276 applicants, 392 ANDAs from 107 applicants, and 3,343 supplements to ANDAs from 222 applicants. FDA estimates that it receives approximately 8,771 claims for categorical exclusions as required under § 25.15(a) and (d) and 22 EAs as required under § 25.40(a) and (c). Based on information provided by the pharmaceutical industry, FDA estimates that it takes sponsors or applicants approximately 8 hours to prepare a claim for a categorical exclusion and approximately 3,400 hours to prepare an EA.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	2,031	4.32	8,771	8	70,168
25.40(a) and (c)	22	1	22	3,400	74,800
Total					144,968

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

Estimated Annual Reporting Burden for Human Foods

Under 21 CFR 171.1, 71.1, 170.39, and 170.100, food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, and submission of a premarket notification for a food contact substance must contain a claim of categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. In 2002, FDA received 12 food additive petitions and 106 food contact substance notifications. FDA estimates that it received approximately 87 claims of categorical exclusions as required under § 25.15(a) and (d) and 31 EAs as required under § 25.40(a) and (c). FDA estimates that it takes petitioners or requestors approximately 8 hours to prepare a claim of categorical exclusion and approximately 210 hours to prepare an EA.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN FOODS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	56	1.6	87	4	348
25.40(a) and (c)	18	1.7	31	210	6,510

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN FOODS[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
Total					6,858

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

Estimated Annual Reporting Burden for Medical Devices

Under 21 CFR 814.20(b)(11), premarket approvals (PMAs) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or §25.34 or an EA under § 25.40. In 1998, FDA received 568 claims (original PMAs and supplements) for categorical exclusions as required under § 25.15(a) and (d), and 0 EAs as required under § 25.40(a) and (c). Based on information provided by less than 10 sponsors, FDA estimates that it takes approximately less than 1 hour to prepare a claim for a categorical exclusion and an unknown number of hours to prepare an EA.

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN FOR MEDICAL DEVICES[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	94	6	568	1	568
25.40(a) and (c)	0	0	0	0	0
Total					568

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

Estimated Annual Reporting Burden for Biological Products

Under 21 CFR 312.23(a)(7)(iv)(e) and 601.2(a), IND and biologics license applications (BLAs) must contain a claim for categorical exclusion under § 25.30 or § 25.31 or an EA under § 25.40. In 2001, FDA received 535 INDs from 376 sponsors, 80 BLAs from 22 applicants, and 837 BLA supplements to license applications from 168 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA estimates that it received approximately 699 claims for categorical exclusion as required under § 25.15(a) and (d), and 2 EAs as required under § 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim for categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product.

TABLE 4.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICAL PRODUCTS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	415	1.68	699	8	5,592
25.40(a) and (c)	2	1	2	3,400	6,800
Total					12,392

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

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and ANADAs, 514.8(a)(1), supplemental NADAs and ANADAs, 511.1(b)(10) investigational new animal drug applications (INADs), 570.35(c)(1)(viii) generally recognized as safe (GRAS) affirmation petitions, and 571.1(c) food additive petitions must contain a claim for categorical exclusion under § 25.30 or § 25.33 or an EA under § 25.40. Since the last OMB approval of these collections of information, FDA's Center of Veterinary Medicine has received approximately 547 claims for categorical exclusion as required under § 25.15(a) and (d) and 19 EAs as required under § 25.40(a) and (c). Based on information provided by industry, FDA estimates that it takes sponsors/applicants approximately 8 hours to prepare a claim for a categorical exclusion and an average of 2,160 hours to prepare an EA.

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	139	3.9	549	8	4,392
25.40(a) and (c)	14	1.4	19	2,160	41,040
Total					45,432

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

Based on information provided by industry, FDA estimates that the combined burden for the Environmental Impact Considerations is as follows:

TABLE 6.—TOTAL ESTIMATED ANNUAL REPORTING BURDEN FOR ALL CENTERS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Burden Hours
25.15(a) and (d)	70,168	348	568	5,592	76,676
25.40(a) and (c)	74,800	6,510	0	6,800	88,110
Total					164,786

Dated: March 10, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–6228 Filed 3–14–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0077]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Emergency Medical Device Shortage Program Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by April 16, 2003.

ADDRESSES: Fax written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202-395-6974, or electronically mail comments to *sshapiro@omb.eop.gov*.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (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.

Emergency Medical Device Shortage Program Survey (OMB Control Number 0910–0491)—Reinstatement

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)), the Commissioner of Food and Drugs is authorized to implement general powers (including conducting research) to carry out effectively FDA's mission. Section 510 of the act (21 U.S.C. 360) requires that domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution register their establishments and list the devices they manufacture with FDA. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. These sections of the act enable FDA to enhance consumer protection from risks associated with medical devices usage that are not foreseen or apparent during the premarket notification and review process.

Subsequent to the events of September 11, 2001, FDA began planning for handling device-related issues related to counterterrorism. One of the activities related to planning for addressing terrorism-related medical device shortages is that FDA, working with medical experts and medical device industry organizations, developed a medical device formulary that identifies which medical devices would be needed in responding to terrorist incidents. The National Pharmaceutical Stockpile Program managed by the Centers for Disease Control appears to have not given adequate consideration to medical devices. Therefore, FDA has developed a plan to ensure adequate availability of medical devices in case of terrorist incidents.

Most particularly, consumable supplies or disposable devices are supplied through large regional distributors. Adequate supplies should be available through these existing commercial supply chains. Problems in supplying these items will be due to logistics. In an emergency, FDA plans to ensure adequate availability of these types of devices by working with industry/distributor organizations. These organizations have actively pursued working relationships with appropriate government agencies to facilitate adequate response in emergency situations.

However, there are more sophisticated or specialized devices, for example, ventilators, defibrillators, and portable x-ray machines are sold directly by the manufacturer but are not sold through independent distributors. For these devices, FDA plans to maintain a database of device manufacturers so that specific contact information can be supplied to emergency response personnel as needed. FDA has identified 17 of these devices and has identified 205 manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Telephone Survey	250	1	250	.5	125

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