GENERAL SERVICES ADMINISTRATION

Public Buildings Service

Notice of Availability of Draft Environment Impact Statement; Proposed Federal Courthouse and Office Building, Eugene/Springfield Metro Area, Lane County, Oregon

Pursuant to section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, as implemented by the Council on Environmental Quality (40 CFR Parts 1500–1508), the General Services Administration (GSA) has filed with the Environmental Protection Agency, and made available to other government and interested private parties, the Draft Environmental Impact Statement (DEIS) for the proposed construction of a 265,290 gross square feet Courthouse and office building including 80 secured parking spaces, located in the urban center of either Eugene/Springfield, Lane County, Oregon.

Two public meetings will be held to solicit comment on the DEIS. They will be held on September 26 Eugene at the Hilton Hotel, 66 East 6th Ave, Eugene, WA, and on September 27th at the Springfield City Hall—Council Meeting Room, 225 5th Street, Springfield, OR.

The DEIS is on file and a copy may be obtained from U.S. General Services Administration, Region 10, Attention: Michael D. Levine, 10PCA, 400 15th Street, SW, Auburn, Washington 98001 (206) 931–7263. A summary of the DEIS can be viewed at the following website: www.northwest.gsa.gov/eugeneusch/intro.htm.

Written comments regarding the Draft Environmental Impact Statement may be submitted until 45 days after publication of the Draft and should be addressed to: John L. Meerscheidt, Herrera Environmental Consultants, 2200 Sixth Ave, Suite 601, Seattle, Washington 98121.

Dated: September 5, 2000.

L. Jay Pearson,

Regional Administrator (10A).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1494]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Classification/Reclassification; Restricted Devices: Analyte Specific Reagents

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on labeling requirements for certain in vitro diagnostic products for manufacturers of analyte specific reagents (ASR's).

DATES: Submit written or electronic comments on the collection of information by November 13, 2000.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at: http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Medical Devices: Classification/Reclassification; Restricted Devices; Specific Reagents—21 CFR Part 809 (OMB No. 0910–0361)—Extension

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires that FDA classify all devices into one of three classes depending on the degree of regulatory control needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are: Class I, general controls; class II, special controls; and class III, premarket approval. Section 502 of the act (21 U.S.C. 352) establishes certain labeling requirements for devices including requirements that the labeling not be false or misleading in any particular, that the labeling contain the established name for the device, and that the labeling contain adequate directions for use. Section 520(e) of the act (21 U.S.C. 360j(e)) provides that FDA may restrict the sale, distribution, or use of a device, if FDA determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. Sections 502(q) and (r) of the act authorizes FDA to regulate the advertising of devices that are restricted under section 520(e) of the act.

FDA restricts distribution of analyte specific reagents to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 as qualified to perform high complexity

testing to manufacturers of in vitro diagnostic products and to organizations that use the tests for reasons other than providing diagnostic information to physicians and patients. FDA has established certain labeling requirements for suppliers of ASR's and some requirements regarding advertising and promotional materials for ASR's. FDA believes the labeling requirements and restrictions on advertising and promotion are necessary to ensure that laboratories developing tests from ASR's have sufficient information to use the ASR's appropriately and to limit specific claims by manufacturers, because these ASR's are intended to be used as ingredients in a variety of ways by laboratories qualified to do high complexity testing.

The most likely respondents to this information collection will primarily be medical device manufacturers of in vitro products, clinical laboratories, and third parties.

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
809.10(e)	300	25	7,500	1	7,500
809.30(d)	300	25	7,500	1	7,500
Totals					15,000

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

The burden is based on the estimate and averaging of five establishments. The number of establishments manufacturing or supplying ASR's ranged from 100 to 500 with the average being 300. Consequently, FDA estimates the number of ASR manufacturers and suppliers subject to the reporting requirements is approximately 300.

The number of ASR's being manufactured was derived by asking the same five establishments. Three of the establishments gave estimates for the number of ASR's that ranged from 5,000 to 10,000, with the average being 7,500.

In order to determine the number of ASR's manufactured by each respondent, FDA used the average number of ASR's manufactured and divided it by the number of ASR manufacturers (7,500 ÷ 300). Consequently, the estimate of the number of ASR's manufactured by each respondent is approximately 25.

FDA estimates for each ASR, it adds approximately 1 additional hour to the design and review process for new labels to conform with the requirements of § 809.10(e) (21 CFR 890.10(e)). FDA also estimates that the total reporting hour burden is approximately 7,500 hours (300 x 25).

FDA estimates for each ASR it adds approximately 1 hour to the preparation and review time for the professional materials to ascertain compliance with § 809.30(d). FDA estimates that the total reporting hour burden for promotional materials is approximately 7,500 (300 X 25).

Dated: September 7, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–23546 Filed 9–13–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1303]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Agreement for Shipment of Devices for Sterilization

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 October 16, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, 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.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control No. 0910–0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices are nonsterile, being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices. The respondents to this collection of information are device manufacturers and contract sterilizers.

In the **Federal Register** of June 12, 2000 (65 FR 36816), the agency requested comments on the proposed collection of information. No significant comments were received.