

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date	9-13-00
Publication Date	9-14-00
Certifier	SPROOSE

[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 *[insert date 60 days after date of publication in the **Federal Register**]*.

**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<sup>1</sup>

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

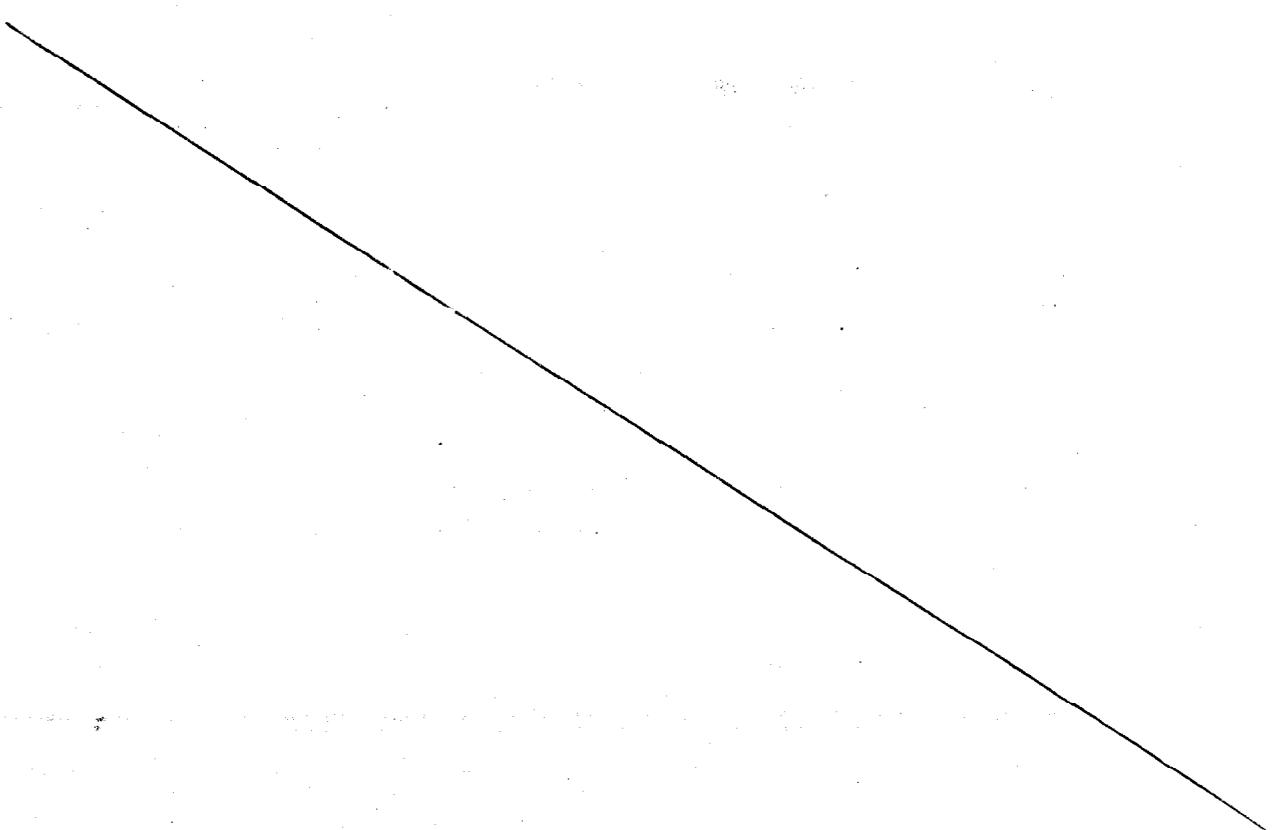
<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

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 ( $7,500 \div 300$ ). 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 ( $300 \times 25$ ).



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  
September 7, 2000.



William K. Hubbard,  
Senior Associate  
Commissioner for Policy,  
Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

