

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 7/21/03  
Publication Date 7/22/03  
Certifier J. COOKE

Food and Drug Administration

[Docket No. 2003N-0302]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Certain Biologics Labeling**

**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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements related to certain biologics labeling requirements.

**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 to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (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:** JonnaLynn Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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 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.

## Certain Biologics Labeling

Under the authority of section 351 of the Public Health Services Act (PHS Act) (42 U.S.C. 262), the biologics regulations require a manufacturer of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce part 601.2 (21 CFR part 601.2). In addition, any changes to labeling are required to be submitted to FDA for review and approval (§ 601.12). For biological products, excluding blood and blood components for transfusion, the container and package labeling requirements subject to the PRA are provided in part 610.60 (21 CFR part 610.60) §§ 610.61, and § 610.62. The collections of information under §§ 601.2, 601.12, 610.60, 610.61, and 610.62 are approved under OMB control number 0910-0338 (expires August 31, 2005). In addition to the labeling requirements prescribed in §§ 610.60 through 610.62 or other labeling regulations (e.g., § 809.10), there are additional container and/or package labeling requirements for certain licensed biological products subject to the PRA: §§ 640.70 and 640.74 (21 CFR 640.70 and 640.74) (Source Plasma), § 640.84 (Albumin), § 640.94 (Plasma Protein Fraction), § 660.2 (Antibody to Hepatitis B Surface Antigen), § 660.28 (Blood Grouping Reagent), § 660.35 (Reagent Red Blood Cells), § 660.45 (Hepatitis B Surface Antigen), and § 660.55 (Anti-Human Globulin).

An example of an additional labeling requirement for each of the specific regulations is as follows:

- Section 640.70(a), the total volume or weight of plasma.
- Section 640.74(b)(3) and (4), the name of the manufacturer of the final blood derivative product for whom it was prepared.
- Sections 640.84(a) and (c), and 640.94(a), the osmotic equivalent.

- Section 660.2(c), name of the recommended test method(s).
- Section 660.28(a) and (b), the name of the antibody or antibodies present.
- Section 660.35(a), (c) through (g), and (i) through (m), information regarding washing of cells, percentage of red blood cells in suspension.
- Section 660.45, name of the recommended test method(s).
- Section 660.55(a) and (b), the name of the antibody or antibodies present.

Form FDA 2567 "Transmittal of Labels and Circulars" is used by manufacturers of licensed biological products to submit with labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. Labeling information is submitted to FDA for review in an application, supplement or, when appropriate, an annual report. Form FDA 2567 is approved under OMB control number 0910-0338.

Based on information obtained from CBER's database system, there is an estimated 350 manufacturers of licensed biological products. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total annual responses are based on the estimated number of submissions for a particular product (e.g., license applications and labeling supplements) received annually by FDA. No applications have been received for most of the listed products in the last couple of years, but FDA is using the estimate of one application in the event one is submitted in the future. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years.

The hours per response is based on past FDA's experience with the various submissions to FDA and includes the time estimated to prepare the various submissions for FDA review and collate the documentation. The burden associated with the additional labeling requirements for submission in a

license application is minimal because the majority of the burden is associated with the requirements under §§ 610.60 through 610.62 or other labeling requirements. FDA estimates that it takes between 10 to 40 hours (average 25 hours) to complete a labeling supplement or annual report for submission to FDA.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

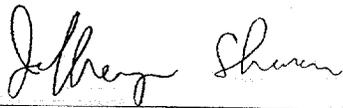
21 CFR Section	Type of Submission	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
640.70(a) and 640.74(b)(3) and (4)	application supplement	5	1	5	2	10
		20	1.5	30	25	750
640.84(a) and (c)	application supplement	1	1	1	1	1
		3	1.25	4	25	100
640.94(a)	application supplement	1	1	1	1	1
		1	1	1	25	25
660.2(c)	application supplement	1	1	1	3	3
		1	1	1	25	25
660.28(a) and (b)	application supplement	1	1	1	6	6
		1	2	2	25	50
660.35(a)(c) through (a)(g) and 660.35 (a)(i) through (a)(m)	application supplement	1	1	1	6	6
		1	1	1	25	25
660.45	application supplement	1	1	1	3	3
		1	1	1	25	25
660.55(a) and (b)	application supplement	1	1	1	6	6
		1	1	1	25	25
Total						1,061

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

Dated: 7-15-03

oc03198

July 15, 2003.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

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

