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

21 CFR Sections	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital, Operating, & Maintenance Costs
101.69	3	1	3	25	75	0
101.70	3	1	3	80	240	$400,000
101.79(c)(2)(ii)(D)	1,000	1	1,000	0.25	250	0
101.79(c)(2)(iv)	100	1	100	0.25	25	0
101.100(d)	1,000	1	1,000	1	1,000	0
101.105 and 101.100(h)	17,000	1.03	17,500	0.5	8,750	0
101.108	0	0	0	40	0	0
Total					996,000	$16,800,000

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Sections	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
101.12(e)	25	1	25	1	25
101.13(q)(5)	265,000	1.5	397,500	0.75	298,125
101.14(d)(2)	265,000	1.5	397,500	0.75	298,125
101.22(i)(4)	25	1	25	1	25
101.100(d)(2)	1,000	1	1,000	1	1,000
101.105(t)	100	1	100	1	100
Total					597,400

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

In the **Federal Register** of January 6, 1993 (58 FR 2927), FDA published a document based on these estimates entitled ''Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations,'' which is the agency's most recent comprehensive review of food labeling costs. The estimates are also based on agency communications with industry and FDA's knowledge of and experience with food labeling and the submission of petitions and requests to the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: October 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27388 Filed 10–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0302]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certain Biologics Labeling

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 (the PRA).

DATES: Fax written comments on the collection of information by December 1, 2003.

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 written 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: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Certain Biologics Labeling

Under the authority of section 351 of the Public Health Services Act (42 U.S.C. 262), the biologics regulations in part 601 (21 CFR part 601) 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 (§ 601.2). In addition, § 601.12 requires that any changes to labeling be submitted to FDA for review and approval. For biological products, excluding blood and blood components for transfusion, the container and package labeling requirements subject to the PRA are provided in §§ 610.60 through 610.62 (21 CFR 610.60 through 610.62). The collections of information under §§ 601.2, 601.12, and 610.60 through 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.*, 21 CFR 809.10), there are additional container and/or package labeling requirements for certain licensed biological products subject to the PRA:

- Sections 640.70 and 640.74 (21 CFR 640.70 and 640.74) (source plasma),
- Section 640.84 (albumin),
- Section 640.94 (plasma protein fraction),
- Section 660.2 (21 CFR 660.2) (antibody to Hepatitis B surface antigen),
- Section 660.28 (blood grouping reagent),
- Section 660.35 (reagent red blood cells),
- Section 660.45 (Hepatitis B surface antigen), and
- Section 660.55 (anti-human globulin).

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

- Section 640.70(a), the total volume or weight of plasma;
- Section 640.74(b)(3) and (b)(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); and
- 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 the Center for Biologics Evaluation and Research's database system, there are 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 that 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 are based on FDA's past 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 and 40 hours (average 25 hours) to complete a labeling supplement or annual report for submission to FDA.

In the **Federal Register** of July 22, 2003 (68 FR 43359), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part	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 (b)(4)	application	5	1	5	2	10
	supplement	20	1.5	30	25	750
640.84(a) and (c)	application	1	1	1	1	1
	supplement	3	1.25	4	25	100
640.94(a)	application	1	1	1	1	1
	supplement	1	1	1	25	25

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

21 CFR Part	Type of Submission	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
660.2(c)	application	1	1	1	3	3
	supplement	1	1	1	25	25
660.28(a) and (b)	application	1	1	1	6	6
	supplement	1	2	2	25	50
660.35(a), (c) through (g), and (i) through (m)	application	1	1	1	6	6
	supplement	1	1	1	25	25
660.45	application	1	1	1	3	3
	supplement	1	1	1	25	25
660.55(a) and (b)	application	1	1	1	6	6
	supplement	1	1	1	25	25
Total						1,061

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

Dated: October 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27389 Filed 10–30–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D–1598]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Suggested Documentation for Substantiating Whether Foods Have or Have Not Been Developed Using Bioengineering

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 (the PRA).

DATES: Fax written comments on the collection of information by December 1, 2003.

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 written 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.

Suggested Documentation for Substantiating Whether Foods Have or Have Not Been Developed Using Bioengineering

On May 29, 1992 (57 FR 22984), FDA (we) published a statement of policy entitled ''Statement of Policy: Foods Derived From New Plant Varieties''(the 1992 policy). The 1992 policy stated that the method of development of a new plant variety, including plants developed using bioengineering, is not information that is material under section 201(n) of the act (21 U.S.C. 321(n)) and, therefore, would not be required in the labeling of food. This conclusion is consistent with our historic interpretation of section 201(n) of the act, in that the method of plant breeding is not required to be disclosed in labeling. In the **Federal Register** of April 28, 1993 (58 FR 25837) (the 1993 information request), we requested additional information on labeling issues that had risen from our 1992 policy. Subsequently, in 1999, we held three public meetings to get public input on our existing policy with regard to its premarket review of foods produced through biotechnology and the labeling of such products. In response to comments that we received on our 1992 policy, the 1993 information request, and the public meetings, we decided to develop guidance for voluntary labeling indicating whether foods have or have not been developed using bioengineering. This guidance will assist manufacturers in labeling foods that have or have not been developed using bioengineering so that the labeling statement is truthful, not misleading, and scientifically valid. The information that the manufacturers will collect is documentation of handling practices so that they can truthfully label their products to indicate, if they so choose, whether the food has or has not been developed using bioengineering.

In general, FDA anticipates that manufacturers claiming that a product is not developed using bioengineered material would substantiate the claim. If validated testing is not available to ensure the absence of bioengineered material for a specific food, we suggest that manufacturers document handling practices to substantiate a claim that a food was not developed using bioengineering, rather than using a ''free''claim. Thus, to substantiate handling practices, the manufacturers