

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—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 BURDEN¹

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.

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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).