

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

<sup>1</sup> 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.*

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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