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]

BILLING CODE 4160–01–S

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

would have to document the source of such foods. Examples of documentation that we anticipate will demonstrate handling practices and procedures about how the food was processed are recordkeeping, certifications or affidavits from farmers, processors, and others in the food production and distribution chain. We are neither suggesting that firms maintain a certain set list of documents nor are we suggesting that anything less or different would likely be considered unacceptable. Rather, we are leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was produced using traditional methods.

Description of Respondents: Manufacturers of foods that were and were not produced using bioengineering.

In the 1993 information request, we requested information on labeling of foods that have or have not been developed using bioengineering. Additionally, in 1999, we held three public meetings to get public input on our existing policy on the labeling of foods produced through biotechnology and the premarket review of such products. In response to comments that we received, we decided to develop guidance for the voluntary labeling of foods indicating if they have or have not been developed using bioengineering. In the **Federal Register** of January 18, 2001 (66 FR 4839) FDA published a 60-day notice requesting public comment on the information collection provisions. The following is a discussion of the comments received and FDA's response to those comments.

Most of the comments agreed that labeling food products as bioengineered or nonbioengineered would result in costs due to segregation, testing, or third-party validation, in addition to label changes. However, some comments said the producers that choose to label their products as nonbioengineered and the consumers that choose to purchase these products should incur these costs. Other comments said that these costs should be borne by the growers, manufacturers, processors, and marketers of bioengineered foods. Who should bear the paperwork burden is not within the scope of the guidance.

One comment stated that FDA underestimated the number of small firms that will choose to label their product as not bioengineered, but will not attempt to make an organic claim. The comment did not offer any evidence to substantiate this claim or give an estimate of how many small firms will choose to make a nonbioengineered claim. FDA's estimate of the number of products that would label their products with a bioengineered claim is based on the number of products making an organic claim and the number of products that are not currently making an organic claim on their label, but are making a statement about bioengineering on their Web site, through a press release, or other venue. The PRA analysis estimates the burden for the expected number of firms making bioengineered claims, however, if more firms choose to make bioengineered claims then the paperwork burden would be higher.

Numerous comments pointed out that mandatory labeling would have high costs for additional activities such as segregation, testing, labeling, quality control, and certification. One comment estimated that these costs could be as high as 6–17 percent of the farmgate price. The paperwork reduction analysis only estimates the paperwork burden associated with voluntary labeling, and so does not dispute these estimates, but does not include them in the analysis.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Operating & Maintenance Costs	Total Hours
893	21	18,753	1	1,781,400	18,753

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

No. of Respondents	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Operating & Maintenance Costs	Total Hours
68	26	1,768	1	53,040	1,768

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

FDA estimates that almost all of the organic producers and manufacturers who have issued statements that they will not use bioengineered ingredients will choose to label, and therefore, will incur the reporting burden. We determined the estimates for the annual reporting burden by using the approximately 18,753 products (16,985 organic products and 1,768 nonorganic products) from producers who may not use bioengineered ingredients in their products. These manufacturers include producers who market to a niche of consumers who choose not to use products with bioengeered ingredients and manufacturers who have stated that they do not use bioengineered ingredients in their products. We estimated that the numbers of firms that will choose to label is 893 (825 firms for organic products and 68 for nonorganic products). We estimated that the manufacturers of these products would choose to state on their label and in their labeling that those products were not developed using bioengineering. Such labeling would increase their paperwork burden. The estimates on the annual reporting burden (table 1 of this document) are based on agency knowledge of, and experience with, food labeling. The 18,753 product estimate may be too low if FDA has been unable to identify all producers that could use nonbioengineering labels or if FDA's labeling guidance encourages producers who have not issued bioengineering statements to now use such statements on the label. On the other hand, this may be an overestimate if some producers, who have been making statements indicating that they will try to use foods that were not developed using bioengineering, choose not to label their products.

We believe that the burden associated with the voluntary labeling of foods that have not been developed using bioengineering would be a one-time burden for the small number of firms that would decide, voluntarily, to add

this additional information to the labels for their products, separate from any other label changes for their products. We estimate that at least 90 percent of firms would coordinate the addition of the statement on the label that their products were not developed using bioengineering with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be included almost entirely in the cost of other voluntary or required labeling changes. The incremental cost for these 803 firms (893 x 90 percent) would be approximately $50 per label for 16,878 labels, or $843,900 total. For the remaining 90 firms that would not coordinate changes with other labeling changes, we estimate that the cost would be approximately $500 per label for 1,875 labels, or $937,500 total. The estimated total operating and maintenance costs in table 1 of this document are, therefore, $1,781,400.

When determining the annual recordkeeping burden (table 2 of this document), we estimated that the number of firms that would maintain records to substantiate labeling that their products were not developed using bioengineering is the same as the number of respondents with the reporting burden minus the number of firms marketing organic products (i.e., 68). We did not include products that are labeled ''organic'' in the estimated annual recordkeeeping burden because according to a proposal in the **Federal Register** of March 13, 2000 (65 FR 13512), issued by the Agriculture Marketing Service of the U.S. Department of Agriculture, a food labeled as ''organic'' would not be permitted to contain bioengineered materials. Therefore, the 16,985 organic products available today would be able to bear a voluntary labeling statement that the food was not developed using bioengineering. Thus, there is no additional paperwork burden to substantiate a claim that a product is not developed using bioengineering for these products. Because most of the nonorganic products whose producers have stated they will not use bioengineered ingredients are made by large firms for whom the verification process is not likely to impose a significant burden relative to the size of their operation, we assume that the paperwork processing time associated with testing or source verification for these products is approximately 1 hour for a total of 1,768 hours per year. Therefore, FDA estimated that the total recordkeeping burden would be 1,768 hours per year. Based on our experience, we have estimated that the overhead and maintenance cost are $30 per hour. The estimated total operating and maintenance cost in table 2 of this document are, therefore, $53,040 total.

Dated: October 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27391 Filed 10–30–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 2, 2004, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Anuja Patel, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776 or e-mail: *patelA@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12544 or 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Psychopharmacologic Drugs Advisory Committee and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee will discuss reports of the occurrence of suicidality (both suicidal ideation and suicide attempts) in clinical trials for various antidepressant drugs in pediatric patients with major depressive disorder (MDD). The committee will consider optimal approaches to the analysis of data from these trials, and the results of analyses conducted to date, with regard to the question of what regulatory action may be needed pertinent to the clinical use of these products in pediatric patients. The committee will also consider further research needs to address questions on this topic.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 26, 2004. Oral presentations from the public will be scheduled between approximately 8:15 a.m. to 9:15 a.m., and 1 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 26, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Anuja Patel at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 23, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–27394 Filed 10–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Medicine Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.