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]

BILLING CODE 4160–01–S

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.