

divested under an order is to be preferred in order to restore competition quickly, the Commission does not yet have the information to evaluate the competitive implications of a proposed divestiture to Central Garden and Pet Supply.

The alleged gene therapy markets involve products now in clinical trials and others that appear to be more distant in time and perhaps more speculative. The proposed complaint also alleges a technology market, comprising the technology that firms use to develop gene therapies. The theory is that the post-merger combination of Sandoz and Ciba Geigy will control such a critical mass of proprietary information that its incentives to cross license will be diminished, either deterring entry or raising the price of it. I would be interested in public comment on these allegations.

Assuming a violation, it is not entirely clear that the proposed licensing relief is preferable or adequate. A divestiture is the preferred remedy in a Section 7 case. The proposed order, among other things, requires a license of the ex vivo patent, also called the Anderson patent, which was licensed to Sandoz by the National Institutes of Health. The merger does not add to the scope of the patent monopoly, and I see no basis in the proposed complaint for this aspect of the relief. Nor is there any apparent reason why a divestiture in these markets could not be accomplished. I look forward to reviewing the comments on this issue as well.

[FR Doc. 97-5 Filed 1-2-97; 8:45 am]

BILLING CODE 6750-01-P

## GENERAL ACCOUNTING OFFICE

### Federal Accounting Standards Advisory Board

**AGENCY:** General Accounting Office.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that the Federal Accounting Standards Advisory Board will meet on Friday, January 17, 1997, from 9:00 A.M. to 4:00 P.M. in room 7C13 of the General Accounting Office building, 441 G St., N.W., Washington, D.C.

The purpose of the meeting is to discuss (1) comments received on the Cost of Capital document, (2) social insurance, (3) Interpretation follow-up, and (4) future agenda items. Also, three new members will be introduced, who

will be replacing three retiring members.

Any interested person may attend the meeting as an observer. Board discussions and reviews are open to the public.

#### FOR FURTHER INFORMATION CONTACT:

Wendy Comes, Acting Executive Director, 750 First St., N.E., Room 1001, Washington, D.C. 20002, or call (202) 512-7350.

Authority: Federal Advisory Committee Act. Pub. L. No. 92-463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101-6.1015 (1990).

Dated: December 30, 1996.

Wendy M. Comes,

*Acting Executive Director.*

[FR Doc. 97-71 Filed 1-2-97; 8:45 am]

BILLING CODE 1610-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 96S-0285]

#### Establishment of a Public Docket for Documents and Other Information Pertaining to Exports and Import-for-Export of Certain FDA-Regulated Products Under the FDA Export Reform and Enhancement Act of 1996

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the establishment of a public docket for documents and other information pertaining to the export and the import-for-export of certain FDA-regulated products (such as drugs, biologics, and devices) under the FDA Export Reform and Enhancement Act of 1996. This action will ensure that this information is equally available to all interested persons on a timely basis.

**ADDRESSES:** The public docket is available under the docket number found in brackets in the heading of this notice and is located in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The public docket may be reviewed between 9 a.m. and 4 p.m., Monday through Friday.

#### FOR FURTHER INFORMATION CONTACT:

Philip L. Chao, Office of Policy (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

**SUPPLEMENTARY INFORMATION:** On April 26, 1996, the President signed the FDA Export Reform and Enhancement Act of 1996 (Pub. L. 104-134) into law. This law significantly alters the statutory requirements for the export of unapproved drugs (including biologics and animal drugs) and devices. The law also permits the importation of components of drugs and devices and food additives, color additives, and dietary supplements into the United States if those components are incorporated into articles ("import-for-export") that are exported in accordance with the Federal Food, Drug, and Cosmetic Act, as amended.

On August 6, 1996, the President signed Pub. L. 104-180, which included, in section 603, minor technical amendments. The public may obtain a document that sets forth the current statutory provisions (combining the pre-existing law with the amendments made in April and August 1996) on FDA's home page on the Internet ([www.FDA.gov](http://www.FDA.gov)).

FDA employees, in the usual discharge of their responsibilities and in response to inquiries and requests from companies, firms, and trade associations, often provide information on FDA's export and import activities. The information provided often addresses historical and current information on statutory or regulatory requirements and on current FDA export and import policies and programs.

To help make information regarding FDA's interpretation and implementation of the FDA Export Reform and Enhancement Act of 1996 available to all interested persons, FDA has developed a mechanism for providing public access to relevant documents and other information created by FDA employees. Specifically, FDA has created a public docket where documents, such as letters on the export of unapproved drugs for investigational use and sent by FDA to various companies and trade associations and guidance to field personnel concerning procedures for articles imported for manufacturing and subsequent export, will be maintained. The documents placed in the public docket are not intended to create or confer any rights for or on any person and do not operate to bind or otherwise obligate or commit FDA or the public to the views expressed. Instead, the documents represent either the agency's current thinking on a particular issue at the time the document was created or at best the best advice of that employee at that time on the issue. (See 21 CFR 10.85(k)).

To ensure that the information in the public docket is kept current, FDA will remove information in the docket that is more than 3 years old. FDA will review the public docket annually to determine its usage; if FDA determines that it is not being used, FDA will discontinue its use.

The public docket is available for public review in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96-35 Filed 1-2-96; 8:45 am]

BILLING CODE 4160-01-F

**Product, Establishment, and Biologics License Applications, Refusal to File; Meeting of Oversight Committee; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of December 19, 1996 (61 FR 67020). The document announced a meeting of the FDA standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications, establishment license applications, and biologics license applications. The agency inadvertently omitted two sentences. This document corrects that error.

**DATES:** The meeting will be held on January 7, 1997.

**FOR FURTHER INFORMATION CONTACT:** Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM-4), Food and Drug Administration, 1401

Rockville Pike, Rockville, MD 20852-1448, 301-594-3079.

In FR Doc. 96-32272, appearing on page 67020 in the Federal Register of Thursday, December 19, 1996, the following correction is made: On page 67020, in the 2d column, under the **SUPPLEMENTARY INFORMATION** caption, in the 3d paragraph, in the 11th line, the sentences "If there are no RTF decisions to review, however, the meeting may be cancelled. Publication of any meeting cancellation will be made only as time permits." are added at the end of the paragraph.

Dated: December 23, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97-91 Filed 1-2-97; 8:45 am]

BILLING CODE 4160-01-F

[Docket Nos. 96N-0325 and 96N-0335]

**Agency Information Collection Activities; Announcement of OMB Approval**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the reinstatement of four collections of information have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. This document announces the OMB approval numbers.

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Wolff, Office of Information Resources Management (HFA-80), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of October 29, 1996 (61 FR 55805 and 55807), the agency announced that the following proposed information collections had been

submitted to OMB for review and clearance:

1. Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers—(21 CFR 108.25(c)(1), (c)(2), (d), (e), (f), and (g); 108.35(c)(1), (c)(2), (d), (e), (f), and (h); 113.60(c); 113.83; 113.87; 113.89; 113.100; 114.80(b); 114.89; and 114.100(a) through (d));

2. Temporary Marketing Permit Applications—(21 CFR 130.17(c) and (i));

3. State Petitions for Exemption From Preemption—(21 CFR 100.1(d)); and

4. State Enforcement Notification—(21 CFR 100.2(d)).

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520), OMB has approved the reinstatement of the information collections and has assigned OMB control numbers as follows:

For Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers, OMB has approved the reinstatement and assigned OMB control number 0910-0037. The approval expires on November 30, 1999.

For Temporary Marketing Permit Applications, OMB has approved the reinstatement of the information collection and assigned OMB control number 0910-0133. The approval expires on November 30, 1999.

For State Petitions for Exemption From Preemption, OMB has approved the reinstatement of the information collection and assigned OMB control number 0910-0277. The approval expires on November 30, 1999.

For State Enforcement Notification, OMB has approved the reinstatement of the information collection and assigned OMB control number 0910-0275. The approval expires on November 30, 1999.