which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, is the subject of approved NDA 50–588 held by AstraZeneca Pharmaceuticals LP (AstraZeneca). CEFOTAN (cefotetan disodium for injection) is indicated for the therapeutic treatment of urinary tract infections, lower respiratory tract infections, skin and skin structure infections, gynecologic infections, intra-abdominal infections, and bone and joint infections when caused by susceptible strains of the designated organisms described in the labeling. FDA approved the NDA for CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, on December 27, 1985. Beginning with the October 2006 update, FDA has listed CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, in the ''Discontinued Drug Product List'' of the Orange Book because AstraZeneca notified FDA that the product was no longer marketed.

B. Braun Medical Inc., submitted a citizen petition dated May 10, 2006 (Docket No. 2006P–0201/CP1), under 21 CFR 10.30, requesting that the agency determine whether CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial (NDA 50–588) was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition (including comments submitted) and reviewing agency records, FDA has determined that CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, was withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, was withdrawn for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA determines that CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to CEFOTAN (cefotetan disodium for injection), equivalent 1 g base/vial and 2 g base/vial, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: May 31, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10959 Filed 6–6–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2007M–0109, 2007M–0006, 2007M–0007, 2007M–0032, 2007M–0049, 2007M–0038, 2007M–0058, 2007M–0086, 2007M–0107, 2007M–0084, 2007M–0108]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010, ext. 152.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and

Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2007, through March 31, 2007. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2007, THROUGH MARCH 31, 2007

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P040051/2007M–0109	Stelkast Co.	STELKAST SURPASS ACETABULAR SYSTEM	May 12, 2006
P050037/2007M–0006	Bioform Medical, Inc.	RADIESSE 1.3 CC AND 0.3 CC	December 22, 2006
P050052/2007M–0007	Bioform Medical, Inc.	RADIESSE 1.3 CC AND 0.3 CC	December 22, 2006
P050018/2007M–0032	Angioscore, Inc.	ANGIOSCULPT SCORING BALLOON CATHETER	January 8, 2007
P060001/2007M–0049	EV3, Inc.	PROTEGE GPS AND PROTEGE RX CAROTID STENT SYSTEMS	January 24, 2007
H060004/2007M–0038	Fujirebio Diagnostics, Inc.	FUJIREBIO MESOMARK ASSAY	January 24, 2007
P050007(S1)/2007M–0058	Abbott Vascular Devices	STARCLOSE VASCULAR CLOSURE SYSTEM	February 2, 2007
P050013/2007M–0086	Tissue Seal, LLC.	HISTOACRYL & HISTOACRYL BLUE TOPICAL SKIN ADHESIVE	February 16, 2007
P980022(S15)/2007M–0107	Medtronic Minimed	GUARDIAN RT & PARADIGM REAL–TIME CONTIUOUS GLUCOSE MONITORING SYSTEMS	March 8, 2007
P050053/2007M–0084	Medtronic Sofamor Danek USA, Inc.	INFUSE BONE GRAFT	March 9, 2007
P060019/2007M–0108	Irvine Biomedical, Inc.	IBI THERAPY COOL PATH ABLATION CATHETER & IBI–1500T9 RF ABLATION GENERATOR	March 16, 2007

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: May 24, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–11002 Filed 6–6–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0208]

Science Board to the Food and Drug Administration; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Science Board to the Food and Drug Administration (Science Board). This meeting was originally announced in the **Federal Register** of May 21, 2007 (72 FR 28499). The amendment is being made to reflect a change in the *Agenda* and *Procedure* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF–33), 5600 Fishers Lane, Rockville, Maryland, 20857, 301–827–6687, *carlos.peña@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 21, 2007, FDA announced that a meeting of the Science Board would be held on June 14, 2007. On page 28499, in the second and third columns, the *Agenda* and *Procedure* portions of document are amended to read as follows:

Agenda: The Science Board will hear about and discuss the agency's bioinformatics initiative and fellowship program. The Science Board will hear about and review the scientific validity of the agency's ''Interim Melamine and Analogues Safety/Risk Assessment'' (*http://www.cfsan.fda.gov/~lrd/fr070530.html*, Docket No. 2007N–0208). The Science Board will then continue its discussion of the review of both the agency's science programs and the National Antimicrobial Resistance Monitoring System (NARMS) Program, from the March 31, 2006, Science Board meeting. Discussions will first include a