ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Year 2000	54	5	1	270

Estimated Total Annual Burden Hours: 270.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collectin of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: ACF Desk Officer.

Dated: June 15, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–15751 Filed 6–21–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–1879]

BetzDearborn; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BetzDearborn has filed a petition proposing that the food additive regulations be amended to expand the safe use of 2-bromo-2-nitro-1,3-propanediol as an antimicrobial for use in food-contact paper and paperboard.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4671) has been filed by BetzDearborn, 4636 Somerton Rd., Trevose, PA 19053. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to expand the safe use of 2-bromo-2-nitro-1,3-propanediol as an antimicrobial for use in food-contact paper and paperboard.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 7, 1999.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–15797 Filed 6–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–1910]

Cytec Industries, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Cytec Industries, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2-[4,6-bis(2,4-dimethylphenyl)-1,3,5-triazin-2-yl]-5-(octyloxy)phenol as a stabilizer for olefin polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4675) has been filed by Cytec Industries, Inc., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2-[4,6-bis(2,4-dimethylphenyl)-1,3,5-triazin-2-yl]-5-octyloxy)phenol as a stabilizer for olefin polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 9, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–15798 Filed 6–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98M–0855, 98M–0722, 98M–0835, 98M–0856, 98M–0857, 98M–0897, 98M–0907, 98M–0972, 98M–0999, 99M–0034, 99M–0894, 99M–0237, 99M–0793]

Medical Devices; Availability of Summaries of Safety and Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval application (PMA) approvals. This list is intended to inform the public of the existence and the availability of summaries of safety and effectiveness of approved PMA's through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Summaries of safety and effectiveness are available on the World Wide Web (WWW) at http://www.fda.gov/cdrh/pmapage.html. Copies of summaries of safety and effectiveness are also available by

submitting a written request to the Dockets Management Branch (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 in the Supplementary Information section of this document, when submitting a written request.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's home page on the Internet (http://www.fda.gov), by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of the PMA approvals and denials announced in that quarter.

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)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) 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 following is a list of all PMA applications for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure as explained previously through March 31, 1999. There were no denial actions during this period. The list provides the manufacturer's name, the generic name or the trade name, and the approval date.

TABLE 1.—LIST OF APPROVED PMA'S FROM SEPTEMBER 25, 1998 THROUGH DECEMBER 31, 1998

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970026/98M–0722	Miriad Ultra Sound, Inc.	Sound Scan 2000 Sound Scan Compact Sound Scan Clinical Bone Sonometer	May 29, 1998
P970034/98M–0855	Ophthalmic Innovations International, Inc.	Ophthalmic Innovations International Modified C-Loop	September 25, 1998
P980017/98M–0835	Possis Medical, Inc.	Perma-Seal Dialysis Access Graft Model 2C20	September 25, 1998
P980018/98M–0857	DAKO A/S	DAKO Herceptest	September 25, 1998
P980025/98M–0856	Logicon RDA	Logicon Caries Detector	September 25, 1998
P960014/98M–0897	Global Therapeutics, Inc.	Magellan-C Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters Model C22020, C22520, C23020, & C23520	Ooctober 5, 1998
P980016/98M–0907	Medtronic, Inc.	Medtronic Gem Dr Model 7271 Dual Chamber Implantable Cardioverter Defibrillator System with Model 9960 (Gem Dr) Applicator	October 9, 1998
P980023/98M–0972	Biotronik, Inc	Phylax Implantable Cardioverter Defibrillator System	October 27, 1998
D970012/98M–0999	American Medical Systems, Inc.	AMS 700 Series Inflatable Penile Prosthesis Product Line; AMS700CX, AMS700CXM, AMS700CX Preconnect, AMS 700 Ultrex and AMS 700 Ultrex Plus	November 2, 1998
P980024/99M–0034	Vysis, Inc.	Path Vysion™; HER–2 DNA Probe Kit	December 11, 1998
P960025/99M–0894	Acromed Corp.	Brantigen I/F Cage® Used with VSP® Spine Plates and Pedicle Screws	February 2, 1999
P980006/99M–0237	Bausch & Lomb Inc.	Pure Vision™ Balafilcon A Visibility Tinted Contact Lens	February 5, 1999
P980041/99M–0793	Beckman Coulter, Inc.	Access AFP Reagents on the Access Immunoassay Analyzer	February 8, 1999

Dated: June 9, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–15755 Filed 6–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs Advisory Committee, Ophthalmic Drugs Subcommittee; 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 Committee: Dermatologic and Ophthalmic Drugs Advisory Committee, Ophthalmic Drugs Subcommittee.

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 July 21, 1999, 8:30 a.m. to 5 p.m.

Location: Hilton Hotel, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Tracy Riley or Angie Whitacre, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting. Current information may also be accessed on the Internet at the FDA Website ''www.FDA.GOV''.

Agenda: The subcommittee will discuss new drug application (NDA) 21–023 (cyclosporine ophthalmic emulsion, 0.05%, Allergan, Inc.), for treatment of moderate to severe keratoconjunctivitis sicca.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by July 16, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before July 16, 1999, 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.Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 16, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–15752 Filed 6–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Public Availability of Information on Clinical Trials for Investigational Devices Intended to Treat Serious or Life-Threatening Conditions; Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting concerning the public availability of information on clinical trials for investigational devices intended to treat serious or life-threatening conditions and the availability of this information in a publicly available data bank. This meeting is being held to assist the agency in preparing a report to Congress required under the FDA Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is inviting written comments and information that may assist FDA in this endeavor.

DATES: The meeting will be held on July 8, 1999, from 1:30 p.m. to 4:30 p.m.; registration will begin at 1 p.m.

ADDRESSES: The meeting will be held at 9200 Corporate Blvd., conference room 020B, Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Robert R. Gatling, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190, ext. 140, FAX 301–594–2977, or e-mail ''rrg@cdrh.fda.gov''.

Those persons interested in attending the meeting should fax or e-mail their registration including name, title, firm name, address, telephone, and fax number to Linda J. Lyons at 301–594–1190, ext. 108 or by fax at 301–594–2977. There is no charge to attend this meeting, but advance registration is requested due to limited seating. If you need special accommodations due to a disability, please contact Linda J. Lyons at least 7 days in advance. Comments at the meeting may be limited in time depending on the number of presenters. Presenters should contact Linda J. Lyons by July 5, 1999.

SUPPLEMENTARY INFORMATION: FDAMA (Pub. L. 105–115) was enacted on November 21, 1997. Section 113(a) of FDAMA amends section 402 of the Public Health Service Act (PHS Act) (42 U.S.C. 282) by adding a new section 402(j). This new section directs the Secretary of Health and Human Services (the Secretary), acting through the Director of the National Institutes of Health (NIH), to establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions.

Section 113(b) of FDAMA (collaboration and report) directs the Secretary, the Director of NIH, and the Commissioner of Food and Drugs to collaborate to determine the feasibility of including device investigations within the scope of the data bank under new section 402(j) of the PHS Act. In addition, section 113(b) of FDAMA directs the Secretary to prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report on the following:

1. The public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(j) of the PHS Act;

2. The adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations is required to be publicly disclosed; and,

3. Such other issues relating to section 402(j) of the PHS Act as the Secretary determines to be appropriate.

Elsewhere in this issue of the **Federal Register**, FDA is inviting written comments and information that may assist FDA in preparing their report to Congress. Those questions should also be considered by those making presentations at the public meeting.

Dated: June 14, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–15758 Filed 6–21–99; 8:45 am]

BILLING CODE 4160–01–F