

annual report. Based on our knowledge of the need to update information on susceptibility test interpretive criteria, susceptibility test methods, and quality control parameters in the labeling for systemic antibacterial drug products for

human use, we estimate that, annually, only 2 applicants will submit the written justification described previously and in the draft guidance. We also estimate that each justification will take approximately 16 hours to

prepare and submit to FDA as general correspondence and as part of the annual report.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours Per Response	Total Hours
Justification submitted as general correspondence and in the annual report	2	1	2	16	32

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.regulations.gov>.

Dated: June 9, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 08–1350 Filed 6–10–08; 11:31 am]

**BILLING CODE 4160–01–S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2008–0321]

**Hospira, Inc., et al.; Withdrawal of Approval of One New Drug Application and Two Abbreviated New Drug Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of one new drug application (NDA) and two abbreviated new drug applications (ANDAs) for edetate disodium injection. The holders of these

applications have agreed in writing to permit FDA to withdraw approval of the applications and have waived their opportunity for a hearing.

**DATES:** Effective June 12, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

**SUPPLEMENTARY INFORMATION:** FDA informed the holders of the following applications that the agency believes a potential problem associated with edetate disodium is sufficiently serious that the following drug products should be removed from the market:

Application No.	Drug	Applicant
NDA 11–355	ENDRATE (edetate disodium) Injection	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045– 5046
ANDA 40–376	Edetate Disodium Injection	Apotex Inc., 150 Signet Dr., Toronto, Ontario, Canada M9L 1T9
ANDA 40–437	Edetate Disodium Injection	Bioniche Pharma, 272 E. Deerpath Rd., suite 304, Lake Forest, IL 60045

Edetate disodium is indicated for the treatment of hypercalcemia and for the control of ventricular arrhythmias associated with digitalis toxicity. Hospira, Inc. (Hospira), Apotex Inc. (Apotex), and Bioniche Pharma (Bioniche) have agreed in writing to permit FDA to withdraw approval of their respective applications (listed in the table of this document), and to voluntarily remove their respective products from the market, under § 314.150(d) (21 CFR 314.150(d)).

On January 16, 2008, FDA issued a public health advisory to alert patients and healthcare professionals about important safety information concerning the drug edetate disodium (see “FDA

Public Health Advisory: Edetate Disodium (Marketed as ENDRATE and Generic Products),” available on the Internet at [http://www.fda.gov/cder/drug/infopage/edetate\\_disodium/default.htm](http://www.fda.gov/cder/drug/infopage/edetate_disodium/default.htm)). As noted in the January 16, 2008, Public Health Advisory, there have been cases where children and adults have died when they were mistakenly given edetate disodium instead of edetate calcium disodium (calcium disodium versenate) or when edetate disodium was used for indications other than those approved by FDA. FDA asked Hospira, Apotex, and Bioniche to voluntarily remove their products (listed in the table of this

document) from the market because of safety concerns.

Hospira’s NDA 11–355 for ENDRATE was initially approved in 1959 solely on the basis of safety. The 1962 amendments to the Federal Food, Drug, and Cosmetic Act (the act) required that drugs be shown to be effective as well. To accomplish this, FDA initiated the Drug Efficacy Study Implementation (DESI) review to evaluate the effectiveness of drugs that had been previously approved on safety grounds alone. In its DESI review of edetate disodium, FDA concluded that edetate disodium was effective for the treatment of hypercalcemia and for the control of ventricular arrhythmias associated with

digitalis toxicity, the two approved indications for the drug (35 FR 437, January 13, 1970).

In a letter dated September 17, 2007, FDA informed Hospira that the agency was reevaluating the safety and efficacy of ENDRATE (edetate disodium) Injection based on reports of fatal medication errors and reports of serious adverse reactions associated with this product. In its September 17, 2007, letter, FDA asked Hospira for additional information related to the safety of ENDRATE (edetate disodium) Injection.

On September 19, 2007, FDA sent letters to Apotex and Bioniche for ANDAs 40-376 and 40-437, respectively, requesting the same information for generic versions of edetate disodium. In a letter dated October 1, 2007, Hospira provided the postmarketing safety information FDA requested on ENDRATE (edetate disodium). In its October 1, 2007, letter, Hospira stated that “[b]ased on the limited indications for ENDRATE (edetate disodium) and the availability of alternate medical products that offer a superior risk-benefit profile,” Hospira determined that “the product is not medically necessary.”

In a letter dated December 7, 2007, under § 314.150(d), FDA asked Hospira to waive its opportunity for a hearing (otherwise provided for under part 314 (21 CFR part 314)) to permit FDA to withdraw approval of NDA 11-355, and to voluntarily remove ENDRATE (edetate disodium) from the market. In a letter dated December 20, 2007, Hospira concurred with FDA’s determination to withdraw approval of NDA 11-355, ENDRATE (edetate disodium), under § 314.150(d); waived its opportunity for a hearing; and agreed to voluntarily remove ENDRATE from the market. Hospira initiated a recall of the product.

In separate telephone conversations on April 8, 2008, FDA asked Apotex and Bioniche, under § 314.150(d), to permit FDA to withdraw approval of ANDAs 40-376 and 40-437, respectively, for generic versions of edetate disodium, and to waive their opportunity for a hearing. Apotex and Bioniche, in letters dated April 9, 2008, and April 17, 2008, respectively, agreed to withdraw their ANDAs under § 314.150(d). Both Apotex and Bioniche indicated that alternative drug products that offer a superior risk-benefit profile are currently available for the approved indications for edetate disodium injection. Both Apotex and Bioniche waived their opportunity for a hearing (otherwise provided under part 314). In its April 9, 2008, letter, Apotex stated it has never marketed ANDA 40-376. In

its April 17, 2008, letter, Bioniche agreed to voluntarily remove its edetate disodium product from the market.

Therefore, under section 505(e) of the act (21 U.S.C. 355(e)), § 314.150(d), and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the applications listed in the table of this document, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 355(a) and 331(d)). On the basis of the circumstances described in this document that led to the withdrawal of approval of the applications listed in the table of this document, the agency will remove these products from the list of drug products with effective approvals published in FDA’s “Approved Drug Products With Therapeutic Equivalence Evaluations,” referred to as the “Orange Book.”

Dated: May 15, 2008.

**Douglas C. Throckmorton,**

*Deputy Director, Center for Drug Evaluation and Research.*

[FR Doc. E8-13273 Filed 6-11-08; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflicts: Musculoskeletal Tissue Engineering.

*Date:* June 16, 2008.

*Time:* 10 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* John P. Holden, PhD, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-496-8551, [holdenjo@csr.nih.gov](mailto:holdenjo@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Orthopaedic Device-associated Immunology.

*Date:* June 20, 2008.

*Time:* 8 a.m. to 9:30 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* John P. Holden, PhD, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-496-8551, [holdenjo@csr.nih.gov](mailto:holdenjo@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: CNS Disorders and Clinical Neuroscience.

*Date:* July 8, 2008.

*Time:* 3 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Alexander Yakovlev, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301-435-1254, [yakovleva@csr.nih.gov](mailto:yakovleva@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Minority Fellowships in Neurobiology and Development.

*Date:* July 14, 2008.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

*Contact Person:* Cathy J. Wedeen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, 301-435-1191, [wedeenc@csr.nih.gov](mailto:wedeenc@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)