Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send two self-addressed adhesive labels to assist the offices in processing your requests. The draft guidance also may be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by facsimile by calling the FAX Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph P. Griffin, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400.

SUPPLEMENTARY INFORMATION:

I. Background

When drugs approved for one use prove safe and effective for treating other conditions, information on the new use should be added to the product labeling as soon as possible. FDA is exploring ways to expedite the development of new and supplemental uses of drug and biological products. The agency believes it can improve the approval process and increase the number of safe and effective new uses being added to drug labeling by doing the following: (1) Clarifying what evidence should be provided in primary and supplemental applications and (2) working with industry to reduce barriers to submitting applications for new uses for their products.

Because some of the information submitted in a supplemental application may be available from the primary application, the agency decided that its first step would be to clarify what information sponsors should provide in applications in general. The draft guidance entitled, ''Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' discusses the clinical evidence that should be provided when submitting a new drug or biological product license application or a supplemental application for a new use of a drug or biological product.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a second draft guidance entitled, ''Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products.'' The draft guidance focuses on the quality and quantity of data that may be adequate to add a new use to the prescribing information for a product used in the treatment of cancer. Cancer treatments often yield potential new uses for marketed drug products.

Although this guidance does not create or confer any right on any person , and does not operate to bind FDA in any way, it does represent the agency's current thinking on clinical evidence of effectiveness for human drug and biological products.

II. Request for Comments

Interested parties may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this draft guidance also is available via Internet using the World Wide Web (WWW) (connect to the CDER home page at http://www.fda.gov/cder and go to the ''Regulatory Guidance'' section, or to the CBER home page at http://www.fda.gov/cber/cberftp.html).

Dated: March 14, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7133 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0095]

Hoffmann-La Roche, Inc., et al.; Withdrawal of Approval of 49 New Drug Applications, 9 Abbreviated Antibiotic Applications, and 36 Abbreviated New Drug Applications; 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 March 27, 1996 (61 FR 13506). The document announced the withdrawal of approval of 49 new drug applications (NDA's), 9 abbreviated antibiotic applications (AADA's), and 36 abbreviated new drug applications (ANDA's). The document inadvertently withdrew approval of NDA 18–962 for Manganese Chloride Injection held by Abbott Laboratories, D–389, Bldg. AP30, 200 Abbott Park Rd., Abbott Park, IL 60064–3537. This document confirms that approval of NDA 18–962 is still in effect, and that the withdrawal of approval of the NDA was in error.

EFFECTIVE DATE: March 27, 1996.

FOR FURTHER INFORMATION CONTACT: Olivia A. Vieira, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

In FR Doc. 96–7309, appearing on page 13506 in the **Federal Register** of Wednesday, March 27, 1996, the following correction is made: On page 13507, in the table, the entry for NDA 18–962 is removed.

Dated: March 14, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–7187 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 96E–0289, 96E–0286, and 96E–0288]

Determination of Regulatory Review Period for Purposes of Patent Extension; DAUNOXOME®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DAUNOXOME® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product DAUNOXOME® (daunorubicin citrate). DAUNOXOME® is indicated as a first line cytotoxic therapy for advanced human immunodeficiency virus (HIV)-associated Kaposi's sarcoma. DAUNOXOME® is not recommended in patients with less than advanced HIV-related Kaposi's sarcoma. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for DAUNOXOME® (U.S. Patent Nos. 5,435,989; 5,441,745; and 5,019,369) from NeXstar Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patent's eligibilities for patent term restoration. In letters dated December 2, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DAUNOXOME® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for DAUNOXOME® is 2,771 days. Of this time, 1,629 days occurred during the testing phase of the regulatory review period, while 1,142 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: September 8, 1988. The applicant claims September 29, 1988, as the date the investigational new drug application (IND) for DAUNOXOME® (IND 31,927) became effective. However, FDA records indicate that the effective date for IND 31,927 was September 8, 1988, which was 30 days after FDA received the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)*: February 22, 1993. The applicant claims February 18, 1993, as the date the new drug application (NDA) for DAUNOXOME® (NDA 50–704) was initially submitted. However, FDA records indicate that NDA 50–704 was submitted on February 22, 1993.

3. *The date the application was approved*: April 8, 1996. FDA has verified the applicant's claim that NDA 50–704 was approved on April 8, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 258 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 20, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before September 17, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–7135 Filed 3–20–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 97M–0082]

Behring Diagnostics, Inc.; Premarket Approval of EMIT® 2000 Cyclosporine Specific Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Behring Diagnostics, Inc., San Jose, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the EMIT® 2000 Cyclosporine Specific Assay. After reviewing the recommendation of the Clinical Chemistry and Toxicology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of October 2, 1996, of the approval of the application.

DATES: Petitions for administrative review by April 21, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Cornelia B. Rooks, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–2436.

SUPPLEMENTARY INFORMATION: On June 29, 1992, Syva Co., San Jose, CA 95161–9013, submitted to CDRH an application for premarket approval of the EMIT® 2000 Cyclosporine Specific Assay. The device is a homogeneous enzyme immunoassay and is indicated for in vitro diagnostic use on the Roche