

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of those portions of NDA 19-627 that provide for a formulation of Diprivan Injectable Emulsion that does not contain the antimicrobial additive disodium edetate is hereby withdrawn effective December 10, 1998.

Dated: November 16, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98-32742 Filed 12-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the 1999 meetings of its 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 (PLA's), establishment license applications (ELA's), and biologics license applications (BLA's). CBER's RTF oversight committee examines all RTF decisions that occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

DATES: The meetings will be held on February, 9, 1999; May 11, 1999; August 10, 1999; and November 9, 1999.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses

on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee meetings continue CBER's effort to promote the timely, efficient, and consistent review of PLA's, ELA's, and BLA's.

FDA's regulations on filing PLA's, ELA's, and BLA's are found in 21 CFR 601.2 and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings, ordinarily, will be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions. If there are no RTF decisions to review, however, the meeting may be cancelled. FDA intends to post any meeting cancellation on the CBER home page at "<http://www.fda.gov/cber/confmeet.htm>".

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all confidential commercial information omitted, may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If, following the committee's review, an RTF decision changes, the appropriate division will notify the sponsor.

Dated: November 30, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-32743 Filed 12-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Medicine Advisory Committee; Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Veterinary Medicine Advisory Committee scheduled for December 10 and 11, 1998. The meeting was announced in the **Federal Register** of November 16, 1998 (63 FR 63740). FDA Center for Veterinary Medicine officials hope to reschedule the Committee meeting for early next year. The meeting will be announced in the **Federal Register** and on the Center for Veterinary Medicine Internet Home Page.

FOR FURTHER INFORMATION CONTACT: Jacquelyn L. Pace, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6650, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12546.

Additional information about the new time and dates for the meeting will be provided on the Center for Veterinary Medicine Internet Home Page (<http://www.fda.gov/cvm>) as soon as they are set.

Dated: December 8, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-33006 Filed 12-8-98; 2:56 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-2088, and HCFA-2540]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed