Board of Governors of the Federal Reserve System, December 4, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–32747 Filed 12–9–98; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Draft Guidelines for HIV Case Surveillance, Including Monitoring HIV Infection and Acquired Immunodeficiency Syndrome (AIDS)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice and Request for Comments.

SUMMARY: This notice announces the availability for public comment of a document entitled ''Draft Guidelines for HIV Case Surveillance, Including Monitoring HIV Infection and Acquired Immunodeficiency Syndrome (AIDS)''.

DATES: Comments must be submitted in writing on or before January 11, 1999. Comments should be submitted to the Technical Information and Communications Branch, Mailstop E–49, Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia 30333; Fax: 404–639–2007; E-mail: hivmail@cdc.gov.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the Draft HIV Case Surveillance Guidelines should be submitted to the CDC National Prevention Information Network, P.O. Box 6003, Rockville, Maryland 20849–6003; telephone (800) 458–5231; or copies can be obtained from the CDC website at http://www.cdc.gov/nchstp/hiv__aids/dhap.htm.

SUPPLEMENTARY INFORMATION: From 1995 to 1996, the incidence of both deaths and opportunistic infections (OIs) due to AIDS declined in the United States for the first time in the history of the epidemic (6 percent for OIs; 23 percent for deaths) as reported in the September 19, 1997, Morbidity and Mortality Weekly Report (MMWR) (Volume 46, pp. 861–867). These declines reflect recent advances in treatment of HIV infection and the provision of care and services that have slowed the progression of AIDS for HIV-infected persons on therapy and the success of HIV prevention and education efforts that have encouraged early diagnosis and have helped to reduce the number of Americans becoming infected with HIV.

In response to these changes in HIV treatment practices and new information needs of public health programs, CDC, the Council of State and Territorial Epidemiologists (CSTE), and most other public health and AIDS organizations have recommended that all States and territories conduct HIV case surveillance in addition to AIDS surveillance. In this manner, the AIDS/HIV epidemic can be tracked more accurately, and appropriate information about HIV/AIDS can be made available to policymakers. As of July 1998, a total of 32 States were conducting HIV case surveillance using the same methods as surveillance for AIDS. Because some States (many with large numbers of AIDS cases) do not report HIV case numbers, interpretations of available HIV data are difficult. To gain more reliable information about the prevalence, incidence, and future directions of HIV infection and the impact on specific populations such as racial and ethnic minorities and women, CDC is proposing that the current surveillance system be expanded to include HIV case reporting for all States and is publishing guidelines that States can use to implement HIV surveillance.

Dated: December 3, 1998.

Jeffrey P. Koplan,

Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–32617 Filed 12–9–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 78G–0133]

Procter & Gamble Co.; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP MF–3710) proposing affirmation that cellulose fines used as a feedstuff for livestock are generally recognized as safe (GRAS).

FOR FURTHER INFORMATION CONTACT: Sharon A. Benz, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6657.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 19, 1978 (43 FR 21727), FDA announced that a petition (GRASP MF–3710) had been filed by the Procter & Gamble Co., 6100 Center Hill Rd., Cincinnati, OH 45224. The petition proposed to amend the GRAS regulations in 21 CFR part 582 to affirm that cellulose fines used as a feedstuff for livestock are GRAS.

Procter & Gamble Co. has now withdrawn the petition without prejudice to a future filing.

Dated: December 4, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–32812 Filed 12–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0221]

Zeneca, Inc.; Withdrawal of Approval of Portion of a New Drug Application Providing for a Formulation of Diprivan Injectable Emulsion Not Containing Disodium Edetate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of those portions of a new drug application (NDA) held by Zeneca, Inc., (Zeneca) for Diprivan (propofol) Injectable Emulsion that provide for a formulation not containing the antimicrobial additive disodium edetate.

EFFECTIVE DATE: December 10, 1998.

FOR FURTHER INFORMATION CONTACT: Virginia G. Beakes, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: By citizen petition dated April 7, 1998 (Docket No. 98P–0221/CP1), Zeneca, 1800 Concord Pike, Wilmington, DE 19850, requested that FDA withdraw 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, stating that the company discontinued marketing the product because of potential contamination problems observed after approval of the NDA. Zeneca waived its opportunity for a hearing.

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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F

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