II. The Risk Assessment and the Establishment of Resistance Thresholds Workshop

The risk assessment and the establishment of resistance thresholds workshop is intended to allow a public discussion of FDA's risk assessment model to evaluate the risk to human health from resistant foodborne pathogens associated with the use of antimicrobials in food-producing animals. The meeting will also discuss FDA's current thinking on the use of this model to establish resistance and monitoring thresholds in food-producing animals. The agency seeks scientific input from experts at the meeting on these issues as well as suggestions for alternative approaches.

III. The Preapproval Studies in AR

The preapproval studies in AR public workshop is intended to allow a public discussion of FDA's current thinking on the appropriate design of preapproval studies in food-producing animals to model the rate and extent of resistance development. The agency will seek suggestions for alternative approaches.

Supportive documents for discussion, including the ''Framework Document,'' can be found on CVM's Internet home page at http://www.fda.gov/cvm. Information including meeting agendas and relevant background information will be posted on the CVM home page in anticipation of each meeting and workshop.

Dated: September 22, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–25083 Filed 9–22–99; 4:28 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; 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: Antiviral Drugs Advisory Committee.

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 November 1, 1999, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Rhonda W. Stover or John B. Schupp, 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 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 20–993, adefovir dipivoxil (Gilead Sciences Inc.), for the treatment of human immunodeficiency virus infection.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 25, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 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: September 17, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–24982 Filed 9–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0834]

Draft Guidance for Industry on Noncontraceptive Estrogen Class Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling.'' The draft guidance is intended to serve as a template for sponsors of estrogen class drug products to ensure that such products contain uniform health care provider and patient labeling information. FDA published a notice of availability of an earlier version of this draft guidance in the **Federal Register** of October 15, 1998 (63 FR 55399). The agency received numerous comments. As a result, the original draft guidance was revised substantially and is being issued in draft for a second time.

DATES: Written comments on the draft guidance document may be submitted by November 26, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry can be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of ''Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Reproductive and Urologic Drug Products, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4260.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling.'' The draft guidance is intended to serve as a template for sponsors of estrogen class drug products to ensure that such products contain uniform health care provider and patient labeling information. Once finalized, this draft guidance will replace the ''Labeling Guidance for Estrogen Drug Products, Physician Labeling'' and ''Labeling Guidance for Estrogen Drug Products, Patient Package

Insert,'' both of which were revised and published in August 1992.

The draft guidance outlines recommended language for the prescribing information for the health care provider and the patient package inserts. Included are black box warnings explaining the increased risk of cancer of the uterus associated with the use of estrogens. Once finalized, the recommendations in this draft guidance should be followed for all approved, pending, and future applications.

In the **Federal Register** of October 15, 1998 (63 FR 55399), FDA announced the availability of an earlier version of this draft guidance. The agency received numerous comments. As a result, the original draft guidance was revised substantially and is being issued in draft for a second time.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on estrogen class labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–24981 Filed 9–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of October 1999.

Name: HRSA AIDS Advisory Committee (HAAC).

Date and Time: October 21–22, 1999; 8:30 a.m.–5:00 p.m.

Place: St. James Hotel, 950 24th Street, NW, Washington, DC 20037.

The meeting is open to the public.

Agenda: Agenda items for the meeting will include finalized recommendations on the reauthorization of the Ryan White CARE Act, Managed Care, Emerging Therapies, and care and service delivery to underserved populations.

Anyone requiring further information should contact Ms. Joan Holloway, HIV/AIDS Bureau, Parklawn Building, Room 7–13, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–5761.

Dated: September 21, 1999.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–24979 Filed 9–24–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–064–1220–00]

Restriction Order for BLM Lands in Wallace L. Forest Conservation Area, Kootenai County, Idaho

AGENCY: Bureau of Land Management, Upper Columbia-Salmon Clearwater District, Idaho.

ACTION: Notice of Restriction Order for BLM Lands in Wallace L. Forest Conservation Area, Kootenai County, Idaho, Order No. ID–060–19.

SUMMARY: By order, the following restrictions apply to the Wallace L. Forest Conservation Area, described as all public land administered by the Bureau of Land Management (BLM) located in the following: Section 31. T.50N., R.2W.; Section 1, T.49N., R.3W.; Section 6, T.49N., R.2W.; Sections 26 and 35, T.50N., R.3W. Boise Meridian. Maps depicting the restricted area are available for public inspection at the BLM, Coeur d'Alene Field Office, 1808 North Third St., Coeur D'Alene, Idaho, 83814.

1. Discharging of firearms for any reason is prohibited.

2. Use of motorized vehicles on other than existing county roads is prohibited.

The authority for establishing these restrictions is Title 43, Code of Federal Regulations, 8364.1

These restrictions become effective immediately and shall remain in effect until revoked and/or replaced with supplemental rules.

Because this Order includes lands previously described under Order #ID060–12, dated 11/1/94, Order ID060–12 is hereby cancelled.

These restrictions do not apply to:

(1) Any federal, state or local official while in the performance of an official duty.

(2) Any Bureau of Land Management employee, agent, contractor or cooperator while in the performance of an official duty.

(3) Any person who is expressly authorized by the Authorized Officer to operate a vehicle in the closed area to access private property.

These restrictions are necessary to protect property and families of adjacent homeowners and to protect the public land from soil erosion had habitat degradation due to off-road vehicle use.

Violation of this order is punishable by a fine not to exceed $1,000 and/or imprisonment not to exceed 12 months.

Dated: September 20, 1999.

Fritz U. Rennebaum,

District Manager.

[FR Doc. 99–25077 Filed 9–24–99; 8:45 am]

BILLING CODE 4310–66–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–956–99–1420–00]

Colorado: Filing of Plats of Survey

September 17, 1999.

The plats of survey of the following described land will be officially filed in the Colorado State Office, Bureau of Land Management, Lakewood, Colorado, effective 10:00 am., September 17, 1999. All inquiries should be sent to the Colorado State Office, Bureau of Land Management, 2850 Youngfield Street, Lakewood, Colorado 80215–7093.

The plat representing the dependent resurvey of portions of the south boundary and subdivisional lines and a metes-and-bounds survey of private land claims in T. 2 N., R. 81 W., Sixth Principal Meridian, Colorado, Group 1168, was accepted September 9, 1999.

The plat representing the dependent resurvey of a portion of the north boundary T. 31 S., R. 68 W., (Sixth Standard Parallel South), portions of the east and west boundaries, and a portion of the subdivisional lines, and the subdivision of certain sections, T. 31 S., R. 68 W., Sixth Principal Meridian, Colorado, Group 1183, was accepted August 19, 1999.

The plat representing the dependent resurvey of a portion of the north boundary T. 31 S., R. 69 W., (Sixth Standard Parallel South), and a portion of the subdivisional lines, and the subdivision of section 1, T. 31 S., R. 69