Services. The meeting will be open to the public.

Name of Committee: Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee).

General Function of the Committee: To advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand Study by the Air Force and provide scientific oversight of the Department of Veterans Affairs (VA) Army Chemical Corps Vietnam Veterans Health Study, and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the Committee is desirable.

Date and Time: The meeting will be held on October 26, 1998, 1 p.m. to 5:30 p.m., and October 27, 1998, 8:30 a.m. to 5 p.m.

Location: Holiday Inn Riverwalk, 217 North St. Marys St., Tarantella Room, rm. 4, San Antonio, TX.

Contact Person: Ronald F. Coene, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12560. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 26, 1998, the VA will present an overview and data collection issues from the pilot study of the Army Chemical Corps Vietnam Veterans Health Study, and discuss considerations for the main health study. On October 27, 1998, the Air Force Health Study presentations will: (1) Provide Cycle 5 Health Exam information, summary, status, and proposed schedule for committee review; (2) report on the latest findings, as well as the status of special studies on half-life, adipose tissue analysis, glucose clamp, and multiple analyte; (3) present proposed measurements for the Cycle 6 Health Exam; (4) report the status of scanning and records maintenance; (5) present a summary of the biological archive; (6) discuss the release of the 1984 preliminary birth defects report; and (7) present the status of public release data.

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 16, 1998. On October 26, 1998, oral presentations from the public will be scheduled between approximately 4:30 p.m. and 5:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 16, 1998, 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.

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 11, 1998.

Sharon Smith Holston,

Acting Commissioner of Food and Drugs.

[FR Doc. 98–25112 Filed 9–18–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0656]

Draft Guidance for Industry on Submission of Abbreviated Reports and Synopses in Support of Marketing Applications; 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 ''Submission of Abbreviated Reports and Synopses in Support of Marketing Applications.'' This draft guidance, which implements section 118 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), is intended to assist applicants who wish to submit abbreviated reports and synopses in lieu of full reports for certain clinical studies, both in marketing applications for new products and in supplements to approved applications. The draft guidance describes which studies may be submitted as abbreviated reports or synopses and describes a format for such submissions. In addition to seeking general comments on the draft guidance, FDA is soliciting comment on three specific issues related to certain types of study submissions and their formats.

DATES: Written comments may be submitted on the draft guidance by November 20, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of the draft guidance 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 Manufacturers Assistance and Communication Staff (HFM–42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. 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. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Debbie J. Henderson, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Submission of Abbreviated Reports and Synopses in Support of Marketing Applications.'' Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) provides that full reports of the investigations used to demonstrate a product's safety and effectiveness be submitted in a new drug application (NDA). Similarly, for biologics license applications (BLA's) FDA often requires that a manufacturer submit full reports to demonstrate that the biological product is safe, pure, and potent.

Section 118 of the Modernization Act, ''Data requirements for drugs and biologics,'' directs FDA to issue guidance on when abbreviated study reports may be submitted in NDA's and BLA's in lieu of full reports. This draft guidance is intended to fulfill the requirements of section 118 of the Modernization Act by providing guidance on the types of studies that may be submitted in abbreviated reports or synopses. This draft guidance also provides recommendations on the formats that should be used.

The NDA regulations at 21 CFR 314.50, which define what must be submitted in an application, do not explicitly define a ''full report,'' but require, among other things, submission of a ''description and analysis of each controlled clinical study pertinent to a proposed use of the drug'' and of ''any other data or information relevant to an evaluation of the safety and effectiveness of the drug product.''

In 1988, FDA issued ''Guidelines for the Format and Content of the Clinical and Statistical Sections of New Drug Applications'' (hereinafter referred to as the Clin/Stat Guideline), which described the contents of a full report of a study. This guidance called for full study reports for studies that contributed effectiveness data as well as safety information. For other studies, sponsors were advised to submit abbreviated reports of the effectiveness results.

In 1996, the International Conference on Harmonisation of the Technical Requirements for Registration of Pharmaceuticals (ICH) ''Guidelines for the Structure and Content of Clinical Study Reports'' (ICH E3) provided an updated description of the contents of a full study report and specific provisions for submitting less-than-full study reports.

Applicants have not used the provisions to submit less-thanfull study reports contained in both the Clin/Stat Guideline and ICH E3 as often as they could have because of difficulties experienced in deciding when a full study report is required by the reviewing body. For example, clinical drug and biologic product development programs often include numerous clinical studies and resulting data that are not intended to contribute to the evaluation of the effectiveness of a product for a particular use and are not needed to support information included in labeling. Accordingly, such studies may be submitted as abbreviated reports or synopses, and this guidance is intended to facilitate their submission.

In developing the guidance, FDA identified the following three issues on which it is specifically seeking public comment:

(1) In describing the format of an abbreviated study report, the draft guidance references selected sections of the study report format in ICH E3 and states that the abbreviated report should include these sections. An alternative approach considered by the agency was to recommend that all of the sections in the ICH E3 clinical study report format be included, but that some of them contain detailed information while others contain only minimal information. Which of these approaches is preferable, or is there another approach that the agency should consider?

(2) The draft guidance indicates that, in general, applicants should submit full reports of negative studies (studies adequately designed to evaluate efficacy that failed to demonstrate efficacy), but provides for the submission of abbreviated reports of such studies in some cases with agreement from the relevant review division. Should abbreviated reports of negative studies be recommended, and, if so, should more detailed information be provided on these trials than is contemplated by the proposed abbreviated report format?

(3) The draft guidance states that in the case of products that are the subject of very limited drug development programs (those with fewer than six studies from any phase of development designed to determine effectiveness including dose comparison trials), full reports of all studies ordinarily should be provided. The rationale for this provision is that, in such programs, even studies less central to the proposed application (e.g., related indication, different dosage form) often form a substantive proportion of the total clinical data base. The agency is seeking comment on whether the proposed definition of ''very limited drug development programs'' is appropriate. Should full reports of all studies be provided for drug development programs with fewer or more than six studies designed to determine effectiveness, or can commenters propose an alternative definition of ''very limited drug development programs?''

This draft guidance represents the agency's current thinking on submission of full study reports, abbreviated reports, and synopses of information related to effectiveness for new drugs and biological products. 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 requirements 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. 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: August 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25102 Filed 9–15–98; 4:19 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Receipt of Application for Endangered Species Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of Receipt of Application for Endangered Species Permit.

SUMMARY: The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

DATES: Written data or comments on these applications must be received, at the address given below, by October 21, 1998.

FOR FURTHER INFORMATION CONTACT: Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act*, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: David Dell, Permit Biologist). Telephone: 404/679–7313; Facsimile: 404/679–7081.

SUPPLEMENTARY INFORMATION:

Applicant: J. D. Wilhide, Arkansas State University, TE002413–0

The applicant requests authorization to take (capture, band, and harass during surveys) the endangered gray bat, *Myotis grisescens*, Indiana bat, *Myotis sodalis*, and Ozark big-eared bat, *Corynorhinus townsendii ingens*, throughout the species' range in Arkansas, for the purpose of enhancement of survival of the species.

Applicant: William Post, Miccosukee Tribe, Miami, Florida, TE002414–0.

The applicant requests authorization to take (harass during surveys) the endangered Cape Sable seaside sparrow, *Ammodramus maritimus mirabilis*, throughout the species range in Everglades National Park, for the purpose of enhancement of survival of the species.

Applicant: Cecil Lamar Comalander, Jr., Milliken Forestry Company, Inc., Columbia, South Carolina, TE002412–0.