ELECTRONIC ELEMENTS FOR SF 525—Continued

Item	Placement*
Sex	
Age	
Date of Consultation	
Narrative Summary—INSTRUCTIONS:	
Include (1) Site of primary and histopathology, (2) Clinical state or class (or exact area if treated for metastasis only), (3) Brief history, (4) Pertinent lab or X-ray findings, (5) Physical findings, (6) Plan of treatment, (7) Dates start and end, (8) Tumor does summary (include special techniques or precautions), (9) Status of tumor at completion of therapy, (10) Tollerance (include medications), (11) Disposition.	
Signature of Physician	
Date (of Signature)	
Relationship to Sponsor	
Sponsor's Name—Last	
Sponsor's Name—First	
Sponsor's Name—MI	
Sponsor's ID Number (SSN or Other)	
Depart./Service	
Organization	
Hospital or Medical Facility	
Records Maintained At	
Patient's Identification	Lower left corner of former.
(Name—last, first, middle; ID No. or SSN; Sex; Date of Birth; Rank/Grade	Lower Left corner of form
Register No.	Lower Left corner of form.
Ward No.	Lower Left corner of form.
Unit Parameters—Field (Allow at least 6 entries)	
Unit Parameters—Unit (Allow at least 6 entries)	
Unit Parameters—Nomenclature (Allow at least 6 entries)	
Unit Parameters—Beam Energy (Allow at least 6 entries)	
Unit Parameters—Calibration Factors (Allow at least 6 entries)	
Unit Parameters—Other Applicable Factors (Allow at least 6 entries)	
Treatment Factors—Field Name (Allow at least 4 entries)	
Treatment Factors—Field Size (Allow at least 4 entries)	
Treatment Factors—SSD/TSD (Allow at least 4 entries)	
Treatment Factors—Angel/ARC (Allow at least 4 entries)	
Treatment Factors—Given Dose (Allow at least 4 entries)	
Time Dose—Point Name (Allow at least 4 entries)	
Time Dose—Dose (Allow at least 4 entries)	
Time Dose—Franctions (Allow at least 4 entries)	
Time Dose—Days (Allow at least 4 entries)	
Time Dose—Inclusive Dates (Allow at least 4 entries)	

*If no placement indicated, items can appear anywhere on the form.

FOR FURTHER INFORMATION CONTACT: CDR Steven S. Kerrick, USN National Naval Medical Center, Department of Ophthalmology, Bethesda, MD 20889–5000 or E-Mail at StevenK966@aol.com.

Dated: November 15, 1999.

Steven S. Kerrick,

Chairperson, Interagency Committee on Medical Records.

[FR Doc. 99–30600 Filed 11–23–99; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4718]

Guidance for Industry on In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling.'' This guidance provides recommendations to sponsors of new drug applications (NDA's) and biologics license applications (BLA's) for therapeutic biologics on carrying out in vivo drug metabolism and metabolic drug-drug interaction studies. The guidance reflects the agency's current view that the metabolism of a new drug should be defined during drug development and that its interactions with other drugs should be explored as part of an adequate assessment of the safety and effectiveness of the drug.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: 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 to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike,

Rockville, MD 20852–1448, FAX: 888–CBERFAX or 301–827–3844. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Shiew–Mei Huang, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5671; or David Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5349.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling.'' A draft of this guidance was published for comment in the **Federal Register** of November 19, 1998 (63 FR 64269). The guidance has been revised after careful consideration of public comments received between November 1998 and March 1999.

Previous guidance from FDA on the use of in vitro approaches to study metabolism and metabolic drug-drug interactions is available in a document entitled ''Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro'' (April 1997). This guidance should be viewed as a companion to this earlier guidance. The earlier guidance addressed techniques and approaches for in vitro studies of drug metabolism and drug interactions and the correlation between in vitro and in vivo studies. This guidance discusses study design, choice of interacting drugs, and data analysis and provides recommendations for dosing and labeling.

This Level 1 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on drug metabolism and drug-drug interactions. 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 statutes, regulations, or both.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. 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 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.

III. Electronic Access

Copies of this 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.

Dated: November 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Poilcy.

[FR Doc. 99–30568 Filed 11–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Meeting of Advisory Committee to the Interagency Task Force to Improve Hydroelectric Licensing Processes

AGENCY: Department of the Interior—Office of the Secretary.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Advisory Committee to the Interagency Task Force to Improve Hydroelectric Licensing Processes will meet on December 8, 1999 at the Department of the Interior. The purpose of the meeting is to:

(1) Update Committee members on the current activities of the Interagency Task Force (ITF);

(2) Review and discuss the ITF Working Groups' draft products on: (i) Studies, (ii) Collaborative Process Guidelines, and (iii) Economics.

DATES: December 8, 1999; 8:30 a.m.–3 p.m.

ADDRESSES: Department of the Interior, Room 7000, 1849 C St. NW, Washington, DC. Security at the building entrance will issue you a visitor's pass and direct you to Room 7000 upon your arrival.

FOR FURTHER INFORMATION CONTACT: Alex Matthiessen, Office of Secretary, Department of the Interior. 202–208–6291.

SUPPLEMENTARY INFORMATION: The Secretary of the Interior and the Chairman, Federal Energy Regulatory Commission, with the concurrence of ITF members, established the Advisory Committee to provide a forum for non-Federal entities to review and provide comments on the deliberations of the ITF. Interested parties are invited to attend the meeting and will be given an opportunity to provide comments.

Alex Matthiessen,

Special Assistant to the Designated Federal Officer.

[FR Doc. 99–30576 Filed 11–23–99; 8:45 am]

BILLING CODE 4310–10–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of the Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for Designation of Critical Habitat for the Woundfin (*Plagopterus argentissimus*) and Virgin River Chub (*Gila seminuda*) within the Virgin River Basis

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: We, the Fish and Wildlife Service, announce the availability of the Final Environmental Assessment and Finding of No Significant Impact for Designation of Critical Habitat for the Woundfin (*Plagopterus argentissimus*) and Virgin River Chub (*Gila seminuda*) within the Virgin River Basin. The proposed Federal action described in the environmental assessment is to formally designate critical habitat for two endangered fishes inhabiting the Virgin River. Both woundfin and Virgin River chub are listed as endangered species under provisions of the Endangered Species Act of 1973, as amended (Act). The designation of critical habitat for woundfin and Virgin River chub is necessary pursuant to the Act and to comply with a court order to make a final determination with regard to these species. On August 27, 1999, in U.S. District Court, District of Colorado, the Court ordered the Service to proceed with the final designation of critical habitat for woundfin and Virgin River chub. Pursuant to that Court Order, we are proceeding with all necessary steps to finalize critical habitat designation for these two species and providing a notice of availability of the Final EA and FONSI. In accordance with Service