

## I. Background

FDA is announcing the availability of a document entitled "Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations," dated February 2003. The guidance announced in this notice finalizes the draft guidance of the title dated November 2001 (67 FR 56831, November 13, 2001).

"Leveraging," as used by FDA, describes formal or informal relationships or agreements with others outside FDA that enhance the agency's ability to meet its public health mission. Leveraged collaborations between FDA and non-FDA partners, such as industry, academia, consumer groups, scientific experts, public health providers, states and other Government agencies, are not new to the agency. For many years, FDA has used collaborations to accomplish a wide variety of tasks related to fulfilling its public health mission. FDA is careful to structure its collaborations so that the agency's regulatory independence, impartiality, and integrity are preserved. Successful collaborations used by FDA and its partners range in size and complexity from simple daylong workshops and training sessions to the creation of cooperatively administered centers that provide critical product-related safety information and expertise, i.e., the National Center for Food Safety and Technology, the Joint Initiative for Food Safety and Nutrition, and the Product Quality Research Institute. Other collaborations involve conducting research to improve the safety, efficacy, purity, or potency of regulated products and convening experts to evaluate emerging public health issues and to recommend actions that should be taken to address the issues.

This guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115). The guidance document represents the agency's current thinking on this topic. 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 statutes and regulations.

## II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the guidance document. Two copies of mailed comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the

brackets in the heading of this document. A copy of 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

Persons with access to the Internet may obtain the guidance document at <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 19, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03-5793 Filed 3-11-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03D-0044]

#### Medical Devices: Draft Guidance for Industry and FDA Reviewers; Statistical Guidance on Reporting Results From Studies Evaluating Diagnostic Tests; 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 and FDA reviewers entitled "Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests; Draft Guidance for Industry and FDA Reviewers." This draft guidance is regarding the submission of premarket notification and premarket approval applications (PMAs) for diagnostic tests. The draft guidance describes some statistically appropriate practices for reporting results from different studies evaluating diagnostic tests and identifies some common practices that may not provide sufficient information to support submission. Special attention is given to describing a practice called discrepant resolution and its associated problems. This draft guidance is neither final, nor is it in effect at this time.

**DATES:** Submit written or electronic comments on this draft guidance by June 10, 2003. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance on a 3.5" diskette to the Division of Small

Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

#### FOR FURTHER INFORMATION CONTACT:

Kristen L. Meier, Center for Devices and Radiological Health (HFZ-542), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-0616.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On February 11, 1998, the Center for Devices and Radiological Health (CDRH) convened a joint meeting of the Microbiology Devices Panel, Hematology and Pathology Devices Panel, Clinical Chemistry and Toxicology Devices Panel, and Immunology Devices Panel of the Medical Devices Advisory Committee. The purpose of the meeting was to obtain recommendations on

\* \* \* appropriate data collection, analysis, and resolution of discrepant results, using sound scientific and statistical analysis to support indications for use of the in vitro diagnostic devices \* \* \* when the new device is compared to another device, a recognized reference method or 'gold standard,' or other procedures not commonly used, and/or clinical criteria for diagnosis \* \* \*

(63 FR 4458, January 29, 1998). Based on discussions from that meeting, this draft guidance describes some statistically appropriate practices for reporting results from different studies evaluating diagnostic tests and identifies common inappropriate practices. The draft guidance also describes a practice called discrepant resolution and its associated problems.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance document represents the agency's current thinking on statistically appropriate practices for reporting results from different studies evaluating diagnostic tests. 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 applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two hard copies of any mailed comments, except that individuals may submit one hard 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 may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

To receive "Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1428) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available

on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets>.

Dated: March 4, 2003.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 03-5792 Filed 3-11-03; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**Receipt of Applications for Permit**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of applications for permit.

**SUMMARY:** The public is invited to comment on the following applications to conduct certain activities with endangered species and/or marine mammals.

**DATES:** Written data, comments or requests must be received by April 11, 2003.

**ADDRESSES:** 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 within 30 days of the date of publication of this notice to: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203; fax 703/358-2281.

**FOR FURTHER INFORMATION CONTACT:** Division of Management Authority, telephone 703/358-2104.

**SUPPLEMENTARY INFORMATION:**

**Endangered Species**

The public is invited to comment on the following application(s) for a permit 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.*). Written data, comments, or requests for

copies of these complete applications should be submitted to the Director (address above).

**PRT-064369.**

*Applicant:* San Francisco Zoological Society, San Francisco, CA.

The applicant requests a permit to import biological samples from ring-tailed lemur (*Lemur catta*) collected in the wild in Madagascar, for scientific research. This notification covers activities conducted by the applicant over a five year period.

The U.S. Fish and Wildlife Service has information collection approval from OMB through March 31, 2004, OMB Control Number 1018-0093. Federal Agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number.

Dated: February 21, 2003.

**Monica Farris,**

*Senior Permit Biologist, Branch of Permits, Division of Management Authority.*

[FR Doc. 03-5862 Filed 3-11-03; 8:45 am]

**BILLING CODE 4310-55-P**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**Letters of Authorization to Take Marine Mammals**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of issuance of letters of authorization to take marine mammals incidental to oil and gas industry activities.

**SUMMARY:** In accordance with section 101(a)(5)(A) of the Marine Mammal Protection Act of 1972, as amended, and the U.S. Fish and Wildlife Service implementing regulations [50 CFR 18.27(f)(3)], notice is hereby given that the following Letters of Authorization to take polar bears incidental to oil and gas industry exploration activities in the Beaufort Sea and adjacent northern coast of Alaska have been issued to the following companies:

Company	Activity	Location	Date issued
Exxon Mobil Prod. Co .....	Exploration .....	Pt. Thomas field studies .....	Apr. 19, 2002.
EnCana Oil and Gas (USA) .....	Exploration .....	McCovey .....	Aug. 13, 2002.
ConocoPhillips Alaska, Inc .....	Exploration .....	Puviaq #1 and #2 .....	Nov. 15, 2002.
Western GeCo .....	Exploration .....	NPR-A .....	Dec. 23, 2002.
ConocoPhillips Alaska, Inc .....	Exploration .....	Titania #1 .....	Dec. 16, 2002.
Fairweather Geophysical .....	Exploration .....	NPR-A and Colville Rvr .....	Dec. 13, 2002.
Anadarko Petroleum Corp. ....	Exploration .....	Hot Ice #1, #2, #3 .....	Dec. 23, 2002.
ConocoPhillips Alaska, Inc .....	Exploration .....	Oberon #1-3, Placer #1-3 .....	Dec. 26, 2002.
PGS Onshore, Inc. ....	Exploration .....	NPR-A .....	Feb. 14, 2002.