Committee Name	Dates of Meetings	Information-Line Code
Obstetrics and Gynecology Devices Panel	June 11–12 September 10–11 December 7–8 January 27–28 April 6–7 July 20–21 October 19–20	12524
Ophthalmic Devices Panel	February 12–13 April 23–24 July 23–24 October 22–23	12396
Orthopaedic and Rehabilitation Devices Panel	January 12–13 April 27–28 July 9–10 October 8–9	12521
Radiological Devices Panel	February 23 May 11 August 17 November 16	12525
National Mammography Quality Assurance Advisory Committee	May 13	12397
Technical Electronic Product Radiation Safety Standards Committee	September 22	12399
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	No meetings planned	12546
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants	April 10–11	12560
Science Board to the National Center for Toxicological Research	March 24–25	12559

Dated: January 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2025 Filed 1–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0021]

Draft Guidance for Industry; Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for Industry: Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products.'' The draft guidance is intended to provide recommendations and offer alternative methods for sterility testing to confirm the integrity of container and closure systems for sterile biological products, human and veterinary drugs, and medical devices. The draft guidance applies only to the replacement of the sterility test with an appropriate container and closure integrity test in the stability protocol, and it is not offered as a replacement for sterility testing for product release.

DATES: Written comments may be provided at any time, however, to ensure comments are considered for the next revision they should be submitted by March 30, 1998.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), 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. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products.'' The draft guidance provides general information on procedures and practices that should be considered when a manufacturer selects alternative methods to confirm sterility during stability studies of sterile biological products, human and veterinary drugs, and medical devices.

All sterile products are required to have adequate container and closure integrity and to remain free from contamination throughout the product's entire dating period. As a consequence

of the limitations of sterility testing, FDA has determined that alternative methods are available that may more reliably confirm the integrity of the container and closure system in the final form throughout the entire dating period.

The draft guidance was prepared jointly by the following Centers: Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM), and Center for Devices and Radiological Health (CDRH). At the request of CBER's Stability and Formulation Committee, representatives from the Centers met on May 19, 1994, to discuss sterility testing as a component of the stability protocol. The ability of containers/packaging to maintain sterility should be proven for all sterile products.

As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements. Alternative approaches may be warranted in specific situations, and certain aspects may not be applicable to all situations. If a manufacturer believes that the procedure described in the draft guidance is inapplicable to a particular method and other procedures are appropriate for FDA's consideration, the manufacturer may wish to discuss the matter further with the agency to prevent expenditure of money and effort on activities that later may be determined to be unacceptable by FDA. FDA will continue to review alternative methods on a case-by-case basis.

The draft guidance represents the agency's current thinking on container and closure integrity testing during stability monitoring for sterile 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. The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time.

II. Request for Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies are to be identified with the docket number found in the brackets in the heading of this document. A copy of 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.

III. Electronic Access

In order to receive the ''Guidance for Industry: Container and Closure Integrity Testing *in Lieu* of Sterility Testing as a Component of the Stability Protocol for Sterile Products'' via your fax machine, call the FAX Information System at 1–888–CBER–FAX or 301–827–3844.

Persons with access to the Internet may obtain the draft guidance document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''. Received comments will be considered in determining whether further revision of the draft guidance document is warranted.

Dated: January 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–2021 Filed 1–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301/496–7057; *Fax:* 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Novel Attenuated Strains Mycobacterium Tuberculosis

CE Barry, Y. Yuan (NIAID).

Serial No.: 60/025,199 filed 10 July 97.

Licensing Contact: Carol Salata, 301/496–7735 ext 232.

This invention provides for novel attenuated strains of *Mycobacterium tuberculosis* and *M. bovis.* Attenuation is achieved by down-regulating the expression of the α-crystallin heat shock protein gene (''acr gene''). This gene is essential for virulence of the organism. Since this strain is isogenic with virulent *M. tuberculosis* but for this deletion, the full complement of antigens remains present and the organism is viable in vitro. The invention provides for vaccines and methods of vaccinating mammals for protection against *Mycobacterium sp.* that cause tuberculosis.

Method of Promoting Tumor Necrosis Using MIG

G Tosato (FDA), J Farber (NIAID), C Sgardari (FDA).

Serial No.: 08/850,914 filed 2 May 97.

Licensing Contact: Jaconda Wagner, 301/496–7735 ext 284.

Monokine induced by IFN–γ (Mig), which is structurally related to interferon-inducible protein 10 (IP–10), has been shown to exhibit antitumor activity. Mig is a member of the α chemokine family. Members of this chemokine family, PF4, PBP, CTAP–III βTG, NAP–2, IL–8 GROα, GROβ, GROγ, and IP–10, have been shown to act as an angiogenic or angiostatic factor. This invention relates to the use of Mig to promote the death of tumor tissue. It also relates to a method of inhibiting angiogenesis at a tumor site using Mig.

This research has been published in Blood 1997 Apr 15;89(8):2635–43 and J Leukoc Biol 1997 Mar;61(3):246–57.

A related case is also available for licensing: Serial No. 08/455,079 filed 31 May 95 entitled ''Interferon-Inducible 10 (IP–10) is a Potent Inhibitor of Angiogenesis''; inventors are G Tosato, AL Angiolillo, and C Sgardari.

Formation of Human Bone In Vivo

PG Robey (NIDR), P Bianco (Universita dell Aquilla), Sa Kuznetsov (NIDR), PH Krebsback (NIDR), DW Rowe (University of Connecticut.

Serial No.: 08/798, 715 filed 12 Feb. 97.

Licensing Contact: Jaconda Wagner, 301/496–7735 ext 284.

This invention provides a model for studying human bone metabolism *in*