

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier R. LEDESMA

Food and Drug Administration

**Termination of Two Food and Drug Administration Advisory Committees:
Medical Imaging Drugs Advisory Committee and the Pharmacy
Compounding Advisory Committee**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of two FDA advisory committees: The Medical Imaging Drugs Advisory Committee, a nonstatutory advisory committee to FDA's Center for Drug Evaluation and Research (CDER), and the Pharmacy Compounding Advisory Committee, a statutory committee to the FDA's Center for Drug Evaluation and Research.

DATES: [*Insert date of publication in the Federal Register.*]

FOR FURTHER INFORMATION CONTACT: Linda Ann Sherman, Director Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

SUPPLEMENTARY INFORMATION: Under its current charter, the Medical Imaging Drugs Advisory Committee will expire on February 28, 2004. The Medical Imaging Drugs Advisory Committee is responsible for: (1) Reviewing and evaluating data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and for use as contrast media in diagnostic radiology and (2) making appropriate recommendations to the

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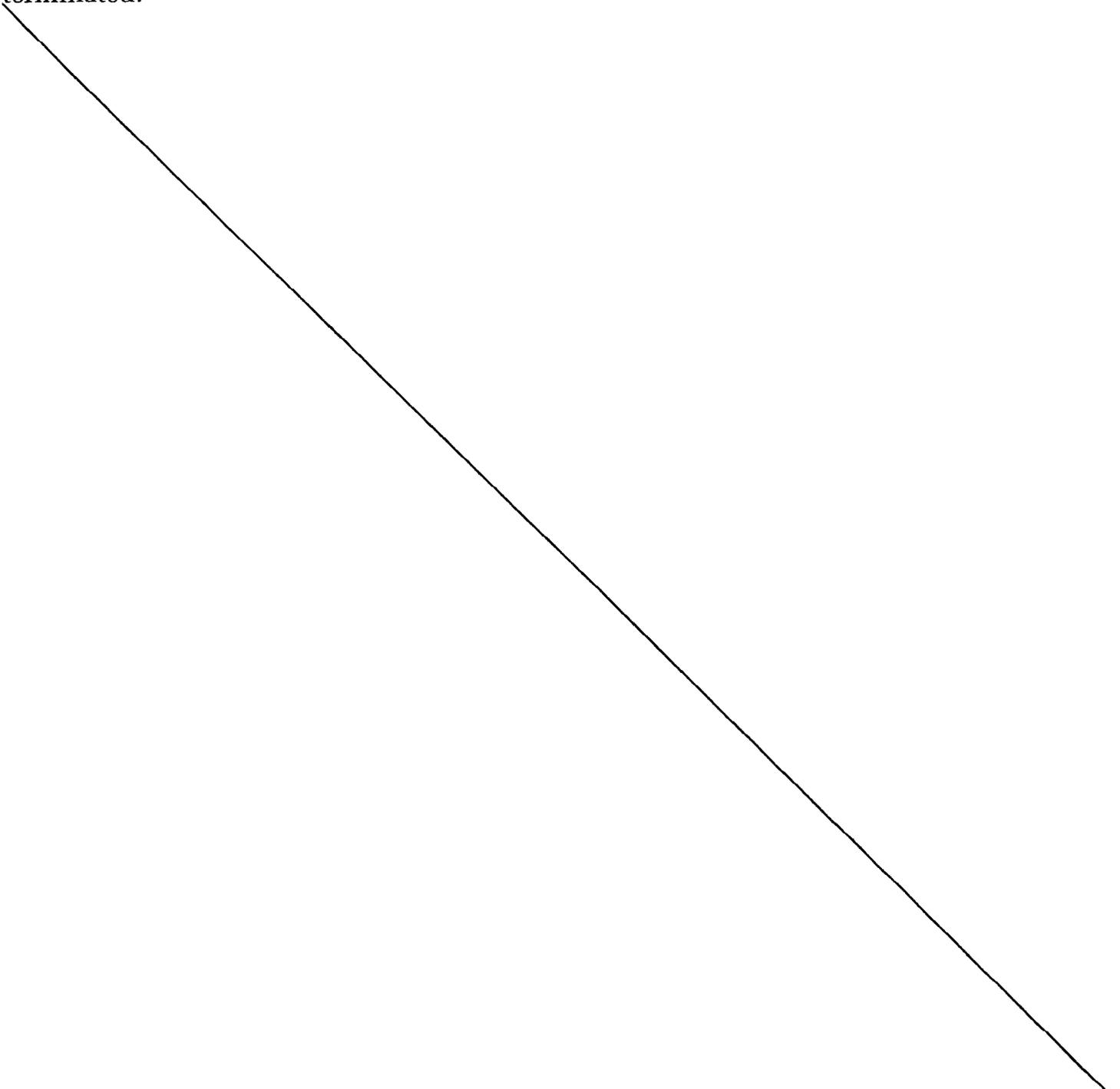
Commissioner of Food and Drugs. The Commissioner has determined that a separate advisory committee for these products is not necessary as these products can be more effectively reviewed by an existing advisory committee or a by a subcommittee of an existing committee with responsibility for providing advice and recommendations regarding the specific systemic product area at issue with a given product.

The charter for the Pharmacy Compounding Advisory Committee was renewed February 3, 2002, for a 2-year term. This Committee was created by section 503A(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353a(d)(1)). Section 503a(d)(1) specifically directed the Secretary of Health and Human Resources to convene and consult an advisory committee on compounding.

On April 29, 2002, the *United States Supreme Court in Thompson, et al. v. Western States Medical Center Pharmacy, et al.*, 122 S.Ct. 1497 (2002), affirmed a decision of the U.S. Court of Appeals for the Ninth Circuit invalidating section 503A of act. Section 503A of the act, enacted as part of the Food and Drug Administration Modernization Act of 1997, exempted drugs compounded by pharmacies from the act's new drug approval, adequate directions for use, and good manufacturing practice requirements if specified conditions, including two restrictions on commercial speech, were met. The Supreme Court held that these two speech related restrictions violate the first amendment to the U.S. Constitution. The Ninth Circuit had also concluded that these unconstitutional speech restrictions may not be severed from the rest of the provisions in section 503A of the act, and that section 503A is invalid in its entirety. Because neither the Government nor the compounding pharmacy plaintiffs sought review of this aspect of the Ninth Circuit's decision,

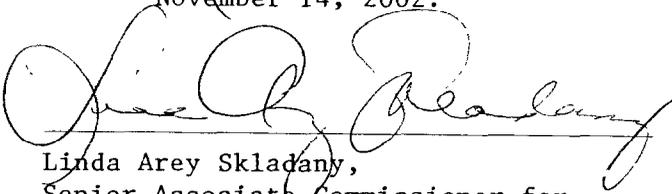
the Supreme Court did not reach the issue. As a result, the Ninth Circuit's invalidation of section 503A of the act in its entirety stands. Because the entire section 503A of the act is invalid, the statutory authorization for an advisory committee on compounding no longer exists.

For the reasons stated previously, the Medical Imaging Drugs Advisory Committee and the Pharmacy Compounding Advisory Committee are terminated.



This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2)).

Dated: November 14, 2002
November 14, 2002.



Linda Arey Skladany,
Senior Associate Commissioner for
External Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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