

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

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Certifier	S. Reese

Food and Drug Administration

[Docket No. 00D-1278]

**Draft Guidance for Industry on Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment." The draft guidance is intended to provide recommendations to industry on the development of drug products for the treatment of female sexual dysfunction (FSD).

**DATES:** Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of this draft guidance for industry can be obtained on the Internet at <http://www.fda.gov/cder/guidance/index.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 Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Lana L. Pauls, Center for Drug Evaluation and Research (HFD-580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4260.

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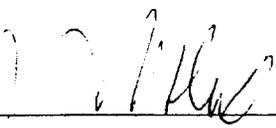
**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled “Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment.” The draft guidance provides recommendations for sponsors designing clinical trials in support of new drug applications for the treatment of FSD. It includes recommendations on the appropriate definition of the patient population to be studied, inclusion and exclusion criteria, the use of scales and questionnaires to assess FSD, and primary endpoints for trials of drug products.

This Level 1 draft guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency’s current thinking on the development of drugs for the treatment of FSD. 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 statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft 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 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: 5.12.00  
May 12, 2000

  
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/ Margaret M. Dotzel  
Acting Associate Commissioner for Policy

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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