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Certifier	Jen Winters

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1266]

**Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling." The draft guidance is intended to clarify for prescription drug manufacturers, relabelers, and distributors FDA's position regarding placing the therapeutic equivalence code on approved FDA product labels and labeling. It also provides recommendations on how to display therapeutic equivalence codes on labels and labeling. Inclusion of a therapeutic equivalence code on prescription drug labels/labeling is voluntary.

**DATES:** Written comments may be submitted 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**ADDRESSES:** Copies of the draft guidance are available on the Internet at "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 Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane,

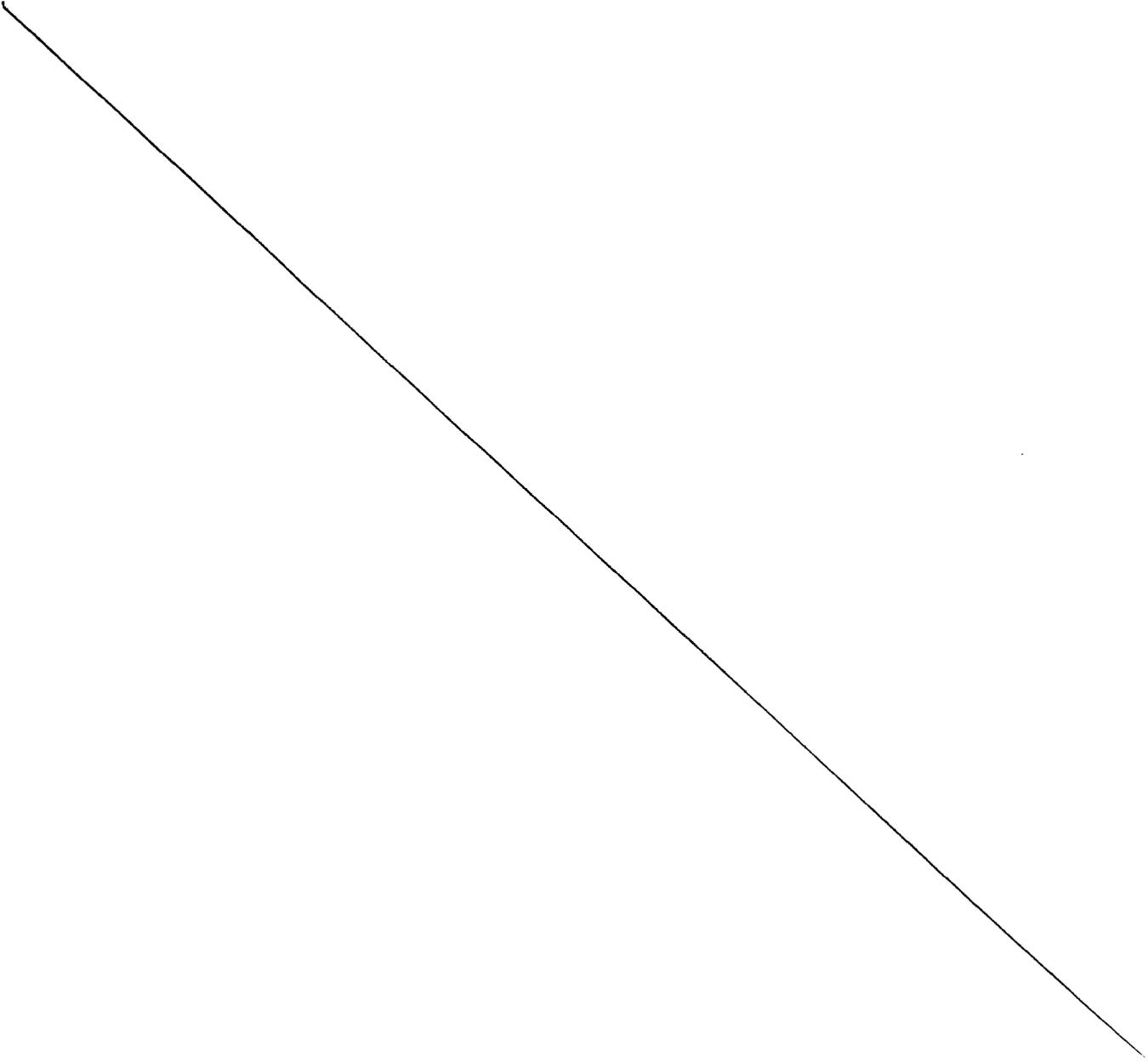
rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jerry Phillips, Center for Drug Evaluation and Research (HFD-610), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3225.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a draft guidance for industry entitled “Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling.” With the repeal of section 301(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(l)) as part of the Food and Drug Administration Modernization Act of 1997, FDA believes that it is legally permissible to allow therapeutic equivalence codes to be placed on drug product labels and labeling. The agency also believes that the use of therapeutic equivalence codes will contribute to the accurate and safe selection of generic products by pharmacists. This draft guidance is intended to: (1) Provide a historical perspective on therapeutic equivalence, (2) describe the process by which the agency advises the public on the therapeutic equivalence of approved drug products, and (3) advise manufacturers, relabelers, and distributors of the preferred format and placement of such information on product labels. Although inclusion of a therapeutic equivalence code on prescription drug labels/labeling normally is voluntary, in certain cases where safety issues are raised, the agency may ask that a code be included.

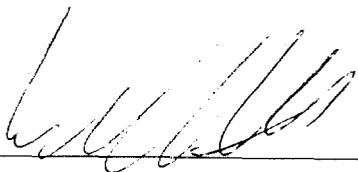
This draft level 1 guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). It represents the agency’s current thinking on placing the therapeutic equivalence code on the labeling of prescription drug products. It does not create or confer any rights for 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.

Interested persons may, on or before (*insert date 60 days after date of publication in the Federal Register*), 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



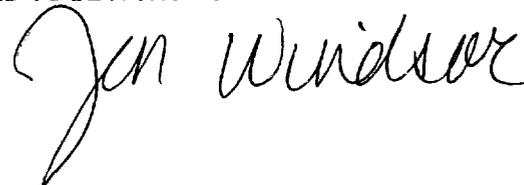
may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 21, 1999  
January 21, 1999



William K. Hubbard  
Associate Commissioner  
for Policy Coordination

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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[FR Doc. 98-<sup>9</sup>???? Filed ??-??-98<sup>9</sup>; 8:45 am]

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