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Certifier	<i>Michael W. Bell</i>

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 98N-1265]

**Federal/State Memorandum of Understanding on Interstate Distribution of  
Compounded Drug Products; Draft; Availability; Reopening of Comment Period**

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

**ACTION:** Notice; reopening of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is reopening until August 2, 1999, the comment period for the draft standard memorandum of understanding (MOU) entitled “Memorandum of Understanding on Interstate Distribution of Compounded Drug Products” (draft standard MOU) that States may enter into with FDA. FDA published a notice of availability of the draft standard MOU in the **Federal Register** of January 21, 1999 (64 FR 3301). The agency is taking this action in response to numerous requests for an extension of the comment period.

**DATES:** Written comments on the draft standard MOU may be submitted by August 2, 1999.

**ADDRESSES:** Copies of the draft standard MOU are available on the Internet at “<http://www.fda.gov/cder/pharmcomp/default.htm>”. Submit written requests for single copies of the draft standard MOU entitled “Memorandum of Understanding on Interstate Distribution of Compounded Drug Products” 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 request. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Fred Richman, Center for Drug Evaluation and Research (HFD-332), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855-2737, 301-827-7292.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 21, 1999 (64 FR 3301), FDA published a notice announcing the availability of a draft standard MOU entitled "Memorandum of Understanding on Interstate Distribution of Compounded Drug Products" that States may enter into with FDA. The draft standard MOU describes the responsibilities of the States and FDA in investigating and responding to complaints related to compounded drug products distributed interstate and addresses the interstate distribution of inordinate amounts of compounded drug products. FDA has developed this MOU in consultation with the National Association of Boards of Pharmacy under provisions of the Food and Drug Administration Modernization Act of 1997. Interested persons were given until March 22, 1999, to submit written comments on the draft standard MOU.

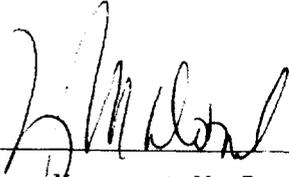
In the **Federal Register** of March 23, 1999 (64 FR 13997), FDA extended the comment period on the draft standard MOU to June 1, 1999.

In response to numerous requests, FDA has decided to reopen the comment period on the draft standard MOU until August 2, 1999.

Interested persons may, on or before August 2, 1999, submit to the Dockets Management Branch (address above) written comments on the draft standard MOU. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified

with the docket number found in brackets in the heading of this document. The draft standard MOU and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6-11-99  
June 11, 1999



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Margaret M. Dotzel  
Acting Associate Commissioner for  
Policy Coordination

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