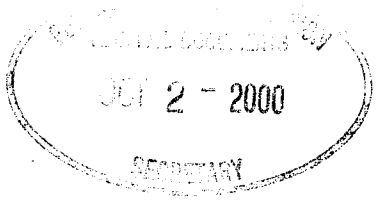
UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



In the Matter of	)	
HOECHST MARION ROUSSEL, INC., a corporation,	)	
CARDERM CAPITAL L.P., a limited partnership,	)	Docket No. 9293
and	)	
ANDRX CORPORATION, a corporation.	)	

ORDER GRANTING MOTIONS BY UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENAS SERVED BY AVENTIS PHARMACEUTICALS, INC. AND ANDRX CORPORATION

I.

Andrx Corporation ("Andrx") and Aventis Pharmaceuticals, Inc. ("Aventis") each served third party subpoenas *duces tecum* on nonparty United States Food and Drug Administration ("FDA"). On August 10, 2000, the FDA filed a motion to quash the subpoena served on it by Andrx. On August 25, 2000, the FDA filed a motion to quash the subpoena served on it by Aventis. Andrx and Aventis each filed their oppositions to these motions on September 11, 2000. The FDA filed a motion for leave to file a reply memorandum in support of its motions to quash and its reply memorandum on September 25, 2000.

The FDA's motion for leave to file a reply is GRANTED. For the reasons set forth below, the FDA's motions to quash the subpoenas served on it by Andrx and by Aventis are GRANTED.

II.

In support of its motion to quash the subpoena served by Aventis, the FDA argues that the FDA's regulations governing document disclosures set forth in 21 C.F.R. Part 20 bar the FDA

from producing documents in response to subpoenas. Although the FDA did not make this argument in support of its motion to quash the subpoena served by Andrx, it is clear from the FDA's reply brief that 21 C.F.R. Part 20 applies with equal force to the Andrx subpoena.

The FDA's regulations governing disclosure of FDA records set forth that whenever a subpoena *duces tecum* has been served upon the FDA, the officer or employee "shall appear in response thereto, respectfully decline to produce the record on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures established in this part." 21 C.F.R. § 20.2(b).

Aventis asserts, and the FDA has confirmed, that Part 20 contains the FDA's Freedom of Information ("FOI") regulations. The FDA asserts that requests for documents pursuant to a subpoena are treated as FOIA requests because 21 C.F.R. § 20.2(b) specifically directs that requests for documents through a subpoena shall be treated as FOI requests. 21 C.F.R. § 20.2(b). Because Andrx and Aventis are required to follow the FDA's statutory procedures for requesting documents set forth in 21 C.F.R. Part 20, the motions of the FDA are GRANTED.

Although courts have held that the Federal Rules of Civil Procedure supercede the regulations promulgated by the FDA, there is no basis for holding that the Commission's Rules of Practice override the FDA's own regulations governing document disclosure. See *Metrex Research Corp. v. United States*, 151 F.R.D. 122, 124 (D. Col. 1993). See also *Cleary, Gottlieb v. Dep't of Health and Human Services*, 844 F. Supp. 770, 787 (D.D.C. 1993) (upholding the FDA's determination that 21 C.F.R. § 20.1 barred testimony by an FDA employee in private litigation and stating that courts should defer to an agency's construction of an administrative regulation); *In re U.S. Bioscience Sec. Litig.*, 150 F.R.D. 80, 82 (E.D. Pa. 1993) ("such 'housekeeping' regulations as 21 C.F.R. § 20.1 have received judicial approval").

The FDA is requested to abide by the agreements made with Andrx and Aventis during their meet and confer sessions and to expedite the FOI process. The trial in this proceeding is scheduled to begin on December 5, 2000. To the extent that Andrx and Aventis do not receive the documents they need from the FDA in a timely manner, requests to extend the close of discovery as it relates to discovery from the FDA will be considered.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: October 2, 2000