## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., a Corporation of the State of New Jersey,

Plaintiff,

v.

) CIVIL ACTION ) NO. 11-73

ELLIOTT L. RICHARDSON, Secretary of Health, Education and Welfare,

) STIPULATION FOR ) DISMISSAL

CHARLES C. EDWARDS, Commissioner of Food and Drugs, Food and Drug Administration, Department of Health, Education and Welfare,

Defendants.

FILED

AUG 2 1973

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Pursuant to Rule 41(a)(l) of the Federal Rules of Civil Procedure, it is hereby stipulated that the above-entitled action may be dismissed without prejudice, each party to bear its own costs.

This Stipulation is premised upon the understanding of the undersigned parties that:

1. The drug, Librax, which is identified in Paragraph 7 of the Complaint in this action, is not "related to" the six drugs listed in Paragraph 34 of said Complaint within the meaning of the "related drug" policy of the Food and Drug Administration which is set forth at 37 Fed. Reg. 23185 et seq (October 31, 1972). Subsequent to the filing of the Complaint in this action, by letter dated February 13, 1973, the Food and Drug Administration rescinded its letter of December 8, 1972,

(Exhibit L to the Complaint), in which the Agency sought to apply its related drug policy to Librax. The Food and Drug Administration will not, in the future, base any adverse action concerning Librax on findings concerning the efficacy of the drugs listed in Paragraph 34 of the Complaint;

- 2. A new drug application for Librax was approved by the Food and Drug Administration on September 1, 1966. At that time, pursuant to the 1962 New Drug Amendments, the Food and Drug Administration determined that Librax was safe and effective for the indications set forth in its labeling;
- above are without prejudice to whatever rights the Food and Drug Administration may have to review its above-referenced approval of the new drug application for Librax. Similarly, plaintiff retains whatever rights it has to interpose procedural or substantive objections to any subsequent Agency action bearing on Librax.

Dated: July 17,1923

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Dated: July 23, 1973

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Dated: July 26, 1973

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