

tion because of the failure of said respondents to furnish responsive answers to interrogatories without good cause being shown. This application was made pursuant to § 382.15 of the Export Regulations (Title 18, Chapter III, Subchapter B, Code of Federal Regulations).

In accordance with the usual practice, the applications for an indefinite denial order was referred to the Compliance Commissioner, Bureau of International Commerce, who after consideration of the evidence has recommended that the application be granted.

The report of the Compliance Commissioner and the evidence in support of the application have been considered. The evidence presented shows that the respondent firm Nema Meet-En Regeltechniek, also known as Nema Kantoran, is a dealer in telecommunication equipment and has a place of business in Amsterdam, The Netherlands; that Ute Hilma Seitz is the sole proprietress of said firm; that the respondent Waldamar Seitz, husband of said Ute Hilma-Seitz, is the individual responsible for the operations of the firm; that the aforesaid Investigations Division is conducting an investigation into the disposition by said respondents of certain strategic U.S. origin commodities known to have been received by them; that said investigation is to ascertain whether said respondents reexported or traded in said commodities in violation of the U.S. Export Regulations. It is impracticable to subpoena the respondents, and relevant and material interrogatories were served on them pursuant to § 382.15 of the Export Regulations. Said respondents have failed to furnish responsive answers to said interrogatories as required by said section, and they have not shown good cause for such failure. I find that an order denying export privileges to said respondents for an indefinite period is reasonably necessary to protect the public interest and to achieve effective enforcement of the Export Control Act of 1949, as amended. This order shall also extend to Ute Hilma Seitz, owner of the firm Nema Meet-En Regeltechniek.

Accordingly, it is hereby ordered:

I. All outstanding validated export licenses in which respondents appear or participate in any manner or capacity are hereby revoked and shall be returned forthwith to the Bureau of International Commerce for cancellation.

II. The respondents, their partners, representatives, agents, and employees hereby are denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction involving commodities or technical data exported from the United States in whole or in part, or to be exported, or which are otherwise subject to the Export Regulations. Without limitation of the generality of the foregoing, participation prohibited in any such transaction, either in the United States or abroad, shall include participation, directly or indirectly, in any manner or capacity: (a) As a party or as a representative of a party to any validated export license applica-

tion; (b) in the preparation or filing of any export license application or reexportation authorization, or any document to be submitted therewith; (c) in the obtaining or using of any validated or general export license or other export control document; (d) in the carrying on of negotiations with respect to, or in the receiving, ordering, buying, selling, delivering, storing, using, or disposing of any commodities or technical data in whole or in part exported or to be exported from the United States; and (e) in the financing, forwarding, transporting, or other servicing of such commodities or technical data.

III. Such denial of export privileges shall extend not only to the respondents, but also to their agents and employees and to any successor and to any person, firm, corporation, or business organization with which they now or hereafter may be related by affiliation, ownership, control, position of responsibility, or other connection in the conduct of trade or services connected therewith.

IV. This order shall remain in effect until the respondents provide responsive answers, written information, and documents in response to the interrogatories heretofore served upon them or give adequate reasons for failure to do so, except insofar as this order may be amended or modified hereafter in accordance with the Export Regulations.

V. No person, firm, corporation, partnership, or other business organization, whether in the United States or elsewhere, without prior disclosure to and specific authorization from the Bureau of International Commerce, shall do any of the following acts, directly or indirectly, or carry on negotiations with respect thereto, in any manner or capacity, on behalf of or in any association with the respondents or any related party, or whereby the respondents or related party may obtain any benefit therefrom or have any interest or participation therein, directly or indirectly: (a) Apply for, obtain, transfer, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to any exportation, reexportation, transshipment, or diversion of any commodity or technical data exported or to be exported from the United States, by, to, or for any such respondent or related party denied export privileges; or (b) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate in any exportation, reexportation, transshipment, or diversion of any commodity or technical data exported or to be exported from the United States.

VI. A copy of this order shall be served upon the respondents.

VII. In accordance with the provisions of § 382.15 of the Export Regulations, the respondents may move at any time to vacate or modify this indefinite denial order by filing with the Compliance Commissioner, Bureau of International Commerce, U.S. Department of Commerce, Washington, D.C. 20530, an appropriate motion for relief, supported by substan-

tial evidence, and may also request an oral hearing thereon, which, if requested shall be held before the Compliance Commissioner in Washington, D.C., at the earliest convenient date.

This order shall become effective forthwith.

Dated: March 14, 1966.

RAUER H. MEYER,
Director, Office of Export Control.

[P.R. Doc. 56-2907; Filed, Mar. 18, 1966;
3:46 a.m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. FDC-D-91; NDA No. 11-791]

HOFFMANN-LA ROCHE, INC.

Madricidin Capsules; Notice of Withdrawal of Approval of New-Drug Application

Hoffmann-La Roche, Inc., Nutley, N.J., 07110, holder of approved new-drug application No. 11-791, and all amendments and supplements thereto, for the drug "Madricidin Capsules (sulfadimethoxine, 125 mg.; phenindamine tartrate, 10 mg.; acetaminophen, 120 mg.; caffeine, 30 mg.)" has waived opportunity for a hearing on the withdrawal of said application.

The Commissioner of Food and Drugs, by virtue of the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (sec. 505(e), 52 Stat. 1053; 21 U.S.C. 355(e)) and delegated to the Commissioner by the Secretary (21 CFR 2.120; 31 P.R. 3008), finds that:

1. The drug Madricidin Capsules is not safe for use upon the basis of which the application was approved on the ground that there have been a number of reports associating the use of sulfadimethoxine, a component of Madricidin Capsules, with the occurrence of Stevens-Johnson syndrome and a number of deaths resulting therefrom; and

2. New information, evaluated together with the evidence available when the application was approved, shows that substantial evidence is lacking that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Therefore, on the basis of the foregoing findings of fact, the approval of new-drug application No. 11-791, and all amendments and supplements thereto, applying to Madricidin Capsules is withdrawn, effective on the date of signature of this document.

Dated: March 11, 1966.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[P.R. Doc. 56-2920; Filed, Mar. 18, 1966;
3:47 a.m.]