

File



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner
5600 Fishers Lane
Room 14-105, HF-7

Food and Drug Administration
Rockville MD 20857

October 1, 1996

Handwritten marks: a vertical line of three 'u' characters on the left, and several 'J' characters scattered in the middle.

- Re: Requests for Designation
1. RESPIFLO Sterile Water for Inhalation Therapy
(Sterile Water for Inhalation, USP)
(Our File: RFD-96-19)
 2. RESPIFLO/S Sterile Water with Saline for Inhalation Therapy
(Sodium Chloride Inhalation Solution, USP)
(Our File: RFD-96-20)

Dear Mr. [J]

We have completed our evaluation of the above-referenced requests for product jurisdiction determinations, submitted by you on behalf of Kendall GmbH (Kendall), accepted for filing on August 2, 1996.

This designation covers two related products: (1) RESPIFLO Sterile Water for Inhalation Therapy (Sterile Water for Inhalation, USP); and (2) RESPIFLO/S Sterile Water with Saline for Inhalation Therapy (Sodium Chloride Inhalation Solution, USP). According to Kendall, both products are sterile and endotoxin-free. The products are packaged in closed systems and are disposable after one use. The products are used for inhalation and humidification during inhalation therapy.

Section VII. D. of the Intercenter Agreement between the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) states that sterile water or saline products in prefilled nebulizers for inhalation therapy are considered to be drugs. Notwithstanding the categorizing of these products as drugs in the Intercenter Agreement, Kendall argues that its products, RESPIFLO and RESPIFLO/S, which are intended to be used with nebulizers and other inhalation delivery systems, should be regulated as medical devices.

Kendall's request for designation recommended that CDRH be the Center with primary jurisdiction for RESPIFLO and RESPIFLO/S, and that the products be reviewed and regulated under the 510(k) premarket notification provisions of The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360(k). Kendall had already submitted two 510(k) notifications for its RESPIFLO and RESPIFLO/S products prior to filing its request for designation. Pursuant to 21 C.F.R. 3.10, this office suspended review of these submissions pending this jurisdictional determination.

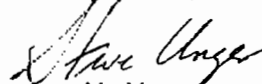
After considering the information provided in the above-referenced request, and consulting with the appropriate officials in CDRH and the CDER, I am designating CDRH as the agency component with primary jurisdiction for the premarket review and regulation of these products. Both RESPIFLO and RESPIFLO/S will be regulated by CDRH under the 510(k) premarket notification provisions of the Act (21 U.S.C. § 360(k)). Any clinical investigations of the products should be conducted in accordance with the investigational device exemption requirements (IDE) in 21 C.F.R. Part 812.

The Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND), Office of Device Evaluation, CDRH, will be the primary review division, and on October 2, 1996, will resume review of the 510(k) notifications already submitted by Kendall. For further information, contact Richard Phillips, Chief, Anesthesiology & Defibrillator Group (HFZ-441), 2098 Gaither Rd, Rockville, MD 20850, or by telephone at 301-443-8609. Please include a copy of this letter in your next submission to CDRH.

This designation represents a departure from the current CDER/CDRH Intercenter Agreement, which states that both purified water and saline in prefilled nebulizers for use in inhalation therapy are regulated as a drugs. (See section VII.D. of the CDER/CDRH Intercenter Agreement.) In the near future, the Intercenter Agreement will be revised to reflect the new agency position.

If you have any questions about this letter, please telephone Megan Foster, of this office, at 301-827-3390.

Sincerely yours,



Steven H. Unger
Deputy, Office of the
Chief Mediator and Ombudsman

cc: Richard Phillips