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TALK PAPER

FOOD AND DRUG ADMINISTRATION
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PROven SERPENTARIUM ENJOINED

Judge Joe Eaton of the U.S. District Court for the Southern District of Florida has permanently enjoined the Miami Serpentarium Laboratories, Inc., William Haast, owner, and Nancy Harrell, principle assistant, from the manufacture and distribution of PROven, a snake venom product promoted by the Serpentarium for the treatment of multiple sclerosis, arthritis and other illnesses.

The March 30 order by Judge Eaton ends a series of efforts by the government to encourage the Serpentarium to adequately manufacture and test PROven before distributing it to the public. In November 1979, the FDA sponsored a public workshop on the experimental use of snake venoms in treating human diseases and invited Haast and experts in venom research, neurologic diseases and arthritis. The experts concluded that PROven had not been adequately standardized and characterized by laboratory testing to allow preliminary clinical testing, let alone commercial distribution.

Nonetheless, the Serpentarium continued to manufacture and distribute the snake venom product to people who were using it without medical supervision.

As a result, FDA requested in September 1980, that the Serpentarium cease manufacture and distribution of the product. (See Press Release P80-41, Sept. 19 1980). FDA's letter said the agency was concerned because:

--the product is potentially toxic, FDA tests having shown that a human dose of PROven kills rabbits and mice.

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-- the serpentarium has not tested the snake venom for sterility or made other important safety tests before distributing it.

-- variable amounts of venom were found from batch to batch, and even different kinds of snake venoms were used.

-- the product was not properly tested and lacked the necessary licenses.

When Haast failed to comply with FDA's request, FDA in October 1980 petitioned the court to order the Miami Serpentarium Laboratories, Inc., et al. to comply with the federal law. Judge Eaton issued a preliminary injunction on Jan. 16, 1981.

Haast continued the manufacture and distribution of the snake venom, however, and made little attempt to have PROven adequately tested and standardized. Accordingly, the government moved for a permanent injunction and asked the court to hold Haast and others in contempt of the January 1981 order.

In the course of these legal proceedings, the Serpentarium admitted that it has not followed accepted manufacturing procedures for making PROven, and that Haast and Harrell are not qualified to manufacture the product. In addition, the Serpentarium agreed that there are no well controlled, scientific studies to establish extraordinary healing qualities for PROven or to establish that it can be safely administered to various patient populations, or what the correct dosage might be.

According to the March 30, 1982 court order, Haast may not cause any formulation of PROven to be shipped or carried outside the State of Florida until he complies with all of the labeling, manufacturing and licensing provisions of the Food, Drug and Cosmetic Act and the Public Health Service Act. The order further provides that PROven, as presently formulated and packaged, may not be distributed even within the State of Florida until it is

properly manufactured, truthfully labeled and tested to assure that its directions for use are adequate. If Haast removes all interstate constituents from PROven (including the inactive ingredients, product containers and closures), he may distribute the product within the State of Florida provided he truthfully labels it.

The court included in the permanent order of injunction a finding that Haast and the Serpentarium had been in contempt of the order of preliminary injunction.

If Haast decides to take the necessary steps to have PROven properly manufactured and tested in controlled trials, the FDA remains willing to assist in planning and evaluating studies of the drug.

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