U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FOR IMMEDIATE RELEASE
March 30, 1987

Food and Drug Administration
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The Food and Drug Administration today advised drug firms manufacturing laxatives containing the drug danthron to immediately discontinue their production and to recall them from retail store shelves.

This decision was based on recent studies showing that chronic administration of high doses of danthron to rats and mice resulted in the development of intestinal and liver tumors and that danthron is, therefore, a potential cause of cancer in humans.

Danthron toxicity in humans has not been specifically demonstrated, but because of the potential risk, FDA has requested an immediate halt to all manufacturing, relabeling, repackaging and further distribution of human drug products containing danthron as an ingredient.

A number of manufacturers of human drug products containing danthron have already voluntarily agreed to remove their products from the market.

All strengths and lots of laxatives containing danthron would be included in the voluntary recall of products. Drugs containing the ingredient danthron are subject to regulatory action under the Food, Drug and Cosmetic Act.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Bethesda MD 20205

URGENT: DRUG RECALL LETTER

Dear Chairman of the Board or President:

This letter concerns danthron-containing drug products offered for human use, which now or have been manufactured, relabeled, repacked or distributed by your firm. All strengths and all lots are included.

A number of manufacturers of human drug products containing danthron have voluntarily agreed to remove their products from the market. This decision was based on conclusions reached by the Food and Drug Administration after reviewing reports received that danthron is a carcinogen in rats and mice and is, therefore, a potential carcinogen in man. Your firm may be one of those taking this voluntary action. For your information, we are enclosing a copy of a public statement issued by the Food and Drug Administration regarding its conclusion that danthron is a carcinogen.

In view of this new information, all human drugs containing danthron are regarded as new drugs within the meaning of Section 201(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Therefore, all drugs containing the ingredient danthron are subject to regulatory action under Sections 502 (misbranding) and 505 (new drug) of the Federal Food, Drug, and Cosmetic Act.

Because of the potential hazard, the Food and Drug Administration requests you immediately cease all manufacturing, relabeling, repackaging and/or distribution of human drug products containing danthron as an ingredient. Further, it is in the public interest that prompt recall be undertaken of all stocks of these products to the retail/dispensing level.

These recalls will be classified by FDA as FDA-Requested Class II. To determine the effectiveness of these recalls, checks should be made to at least ten (10) percent of the total number of your consignees (Level C) as defined in 21 CFR 7.42(b)(3)(iii). The complete Recall Guidelines are found in Title 21 of the Code of Federal Regulations (21 CFR 7.40-7.59).

Our local and District Office will contact you concerning your proposed recall strategy if you are a marketer of any Danthron-containing drug product(s).

Sincerely yours,

John M. Taylor
Associate Commissioner
for Regulatory Affairs

Enclosure:
Public Statement Re Carcinogenicity
of Danthron