



October 6, 2000

Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

7017 '00 OCT 12 P1:37

Docket No. 98N-0337

APPLICATION FOR EXEMPTION

Re: Request for Exemption from 21 CFR 201.66 (OTC Drug Product Labeling)

Subject: L. Perrigo Company (Perrigo)
Day Time Liquid-Filled Capsules (Perrigo product code 389)

Statement of Purpose

Pursuant to 21 CFR 201.66(e), Perrigo requests an exemption from 21 CFR 201.66(c)(8), concerning the labeling of inactive ingredients of its Day Time Liquid-Filled Capsules over-the-counter drug product (Perrigo product code 389). This request is submitted because it is impracticable to list all the inactive ingredients when an OTC drug manufacturer uses multiple suppliers. Two manufacturers supply the Day Time product to Perrigo. While the active ingredients are identical, the inactive ingredients vary slightly. Perrigo is requesting that the Food and Drug Administration permit the use of the phrase "May contain" on the product label to reflect those inactive ingredients that may differ in the formulas manufactured by the two suppliers. The use of the proposed "May contain" statement would not affect the product's safety or efficacy. The exemption would apply to all current and future SKUs of the Day Time product. The proposed labeling would meet all other labeling requirements as outlined in 21 CFR 201.66.

Setting

Perrigo is the nation's largest manufacturer of over-the-counter (OTC) pharmaceutical products for the store brand market. These products are sold by retail supermarkets, drugstores and mass merchandise chains under their own labels.

History and Background

Prior to the Food and Drug Administration Modernization Act of 1997, it was industry practice to utilize "May contain" or "May also contain" in the inactive ingredients listing section to indicate those inactive ingredients that differed between suppliers. Following the Voluntary Codes and Guidelines of the Consumer Healthcare

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Products Association, formerly Non-Prescription Drug Manufacturer's Association, Perrigo had the ability to develop one label, which reflected the inactive ingredients of products sourced from two suppliers. Currently, 21 CFR 201.66(c)(8) does not provide this labeling option.

Process

Perrigo does not manufacture liquid-filled capsules. Perrigo purchases the Day Time Liquid-Filled Capsules from two manufacturers. The use of multiple sources ensures an adequate and continuous supply of product. The product's active ingredients supplied by each manufacturer are identical. The colors used in the formula are the inactive ingredients that vary.

Options considered

Source the material from one supplier. If the single supplier were unable to maintain an adequate supply, the company would incur significant business risk by not having a second source available.

Maintain an inventory of separate labeling for each supplier. Due to the number of SKUs for this product, Perrigo cannot reasonably maintain two labeling versions for each retail customer. This would consume a significant amount of company resources including capital dollars and manpower. Finished good inventory would increase and the labor hours used to create and maintain the additional bills of material would double. Considerable resources would also be expended to create the additional preprinted materials. Due to the increased finished good and preprinted inventory, additional warehouse space would be needed. In addition, when preprinted labeling is revised, such as happens when a monograph changes, the cost of the conversion would double. Because of the higher costs incurred, there would be a negative effect on the company's customers, and ultimately to the consumer.

Direct the suppliers to manufacture a single formula. Each supplier's formula was developed within the constraints of their available equipment and processes. A change to a new formula would be expensive, time consuming and, in some cases, impossible. It would be impractical and an undue burden for a manufacturer to repeat the development process to modify a formula without realizing any benefits. The added costs would be passed to Perrigo and ultimately to the consumer.

Obtain an exemption from 21 CFR 201.66(c)(8). An exemption from 21 CFR 201.66(c)(8) would allow the use of the phrase "May contain". This option would be used with little or no impact to a consumer because all inactive ingredients that are potentially in the product would be listed; no inactives would be omitted. The consumer could choose to purchase the product based on the inactive ingredients listed. Perrigo and its suppliers would continue to operate in a cost-effective manner. Consumers would continue to buy safe and effective products without undue additional costs and with the requisite product ingredient information.



Ingredient Listings

The active ingredients for the product from both suppliers are acetaminophen 250 mg, dextromethorphan hydrobromide 10 mg and pseudoephedrine hydrochloride 30 mg.

The inactive ingredients of Day Time Liquid-Filled Capsules from the two suppliers are:

Supplier 1 inactive ingredients: edible ink, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, D&C yellow no. 10 and FD&C red no. 40

Supplier 2 inactive ingredients: edible ink, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol and FD&C yellow no. 6

Proposed Labeling of Inactive Ingredients

Inactive ingredients edible ink, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol. May contain D&C yellow no. 10, FD&C red no. 40, FD&C yellow no. 6.

If there are any questions concerning this request, please contact me by phone at (616) 673-7595 or fax at (616) 673-7655. Thank you for your attention to this matter.

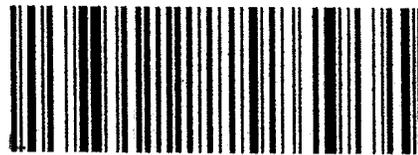
Sincerely,
L. PERRIGO COMPANY

David Jespersen
Director of Technical Affairs

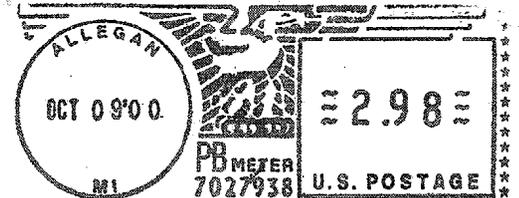
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