



AUG 7 2002

Arent Fox Kintner Plotkin & Kahn, PLLC
Attention: Peter S. Reichertz, Esquire
1050 Connecticut Avenue, NW
Washington, DC 20036-5339

RE: Docket No. 98N-0337
Application for Exemption
APP 42

Dear Mr. Reichertz:

We are responding to your application for exemption (APP) 42, dated June 11, 2002, on behalf of Ricola (USA), Inc. of Morris Plains, New Jersey and Ricola Ag of Laufen, Switzerland. You are requesting a deferral of time for compliance with 21 CFR 201.66 (Drug Facts Rule) until December 31, 2002, for the 10-count stick of Ricola Natural Herb Cough Drop product, which is manufactured and labeled in Switzerland for export to the United States. In your deferral application, you included the current labeling text and the text of the new draft labeling for this product.

You mentioned that Ricola mistakenly believed that the Food and Drug Administration (the agency) was considering an exemption from 21 CFR 201.66 for "convenience-size" packages, which would have included this product. You indicated as soon as Ricola became aware on April 10, 2002, that this product would not necessarily be considered a "convenience-size" package, the company began developing new labeling for this 10-count product to comply with the Drug Facts Rule. However, you stated that in order to sell through its current substantial labeling inventory of the product and implement the revised label for its Natural Herb Cough Drops in a 10-count stick, Ricola requires additional compliance time beyond May 16, 2002, to December 31, 2002.

Your deferral request indicated that the company would start to ship new product to the United States in the 3rd to 4th quarter and begin commercial distribution in the 1st quarter of 2003. For the reasons provided in your application, the agency is, as a matter of enforcement discretion, granting your request for a deferral from the "Drug Facts" labeling requirements in 21 CFR 201.66. We intend to exercise enforcement discretion for the product identified in APP 42 until December 31, 2002. At the end of this deferral period, the labeling for this product must comply with the requirements of 21 CFR 201.66 at the time the product is initially introduced or initially delivered for introduction into interstate commerce in the United States.

98N-0337

ANS 18

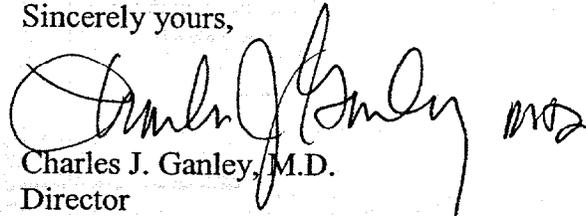
With regard to the draft Drug Facts labeling included in this deferral application, we have the following comments to assist Ricola as it develops its new labeling for the Ricola Natural Herb Cough Drops in a 10-count stick package.

1. On the Principal Display Panel (PDP) of this package, the sponsor should use the officially recognized USP dosage form when stating the net quantity of contents contained in the package (e.g., "10 Lozenges"). "Drop" is not a recognized dosage form for this type of product. In addition, the Agency recommends that the sponsor add the phrase "Menthol Lozenge" before the phrase "Cough Suppressant" as part of the statement of identity of this product.
2. Under the headings *Active ingredient* and *Directions*, the dosage form should be identified as a "lozenge," as specifically identified in the *Directions* section of the OTC drug monograph for antitussive drug products (21 CFR 341.74(d)(2)(iii)).
3. Under the heading *Active Ingredients*, no comma should appear between "Menthol" and "4.8 mg".
4. Under the heading *Purpose*, the first letter of the word "Suppressant" should appear in lower case.
5. Under the warning subheading "*Ask a doctor before use if you have*", the phrase "chronic bronchitis" that appears in the first bulleted statement can be deleted.
6. Under the heading *Directions*, the corresponding dosing information for "adults and children 6 years and older" should be revised by either (a) adding a bulleted symbol before the phrase "take 2 lozenges every hour" and placing each bulleted statement in this section of the dosing table in vertical alignment; or (b) replacing the two bulleted symbols in this section of the dosing table with semicolons.
7. Under the heading *Other information*, the first letter in the word "Store" should appear in lower case.
8. The *Inactive ingredient* information is not correctly placed in the Drug Facts box. This heading and subsequent information must follow the heading *Other information* as set forth in 21 CFR 201.66(c). This can be done by having the information appear immediately below the heading *Other information* or within a separate box entitled "*Drug Facts (continued)*" that would appear where the UPC is currently located. In addition, a visual graphic is needed to signal continuation of the Drug Facts labeling to a second box, if this approach is used.
9. The background within the Drug Facts box should appear as a single color (i.e., white or other light, neutral color, contrasting background) as set forth in 21 CFR 201.66(d)(3). It may be necessary to reconsider the design of the product's labeling or the location of the Drug Facts box in that labeling.

If you have any comments or questions regarding this deferral and the agency's comments concerning the company's draft labeling, please reference the docket and application for exemption numbers and submit them to the Dockets Management Branch

(HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville,
MD 20852. I hope this information is helpful.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Charles J. Ganley M.D.", with a stylized flourish at the end.

Charles J. Ganley, M.D.

Director

Division of OTC Drug Products

Office of Drug Evaluation V

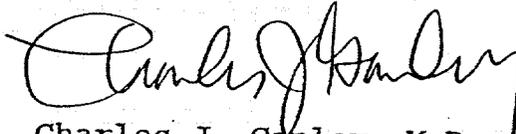
Center for Drug Evaluation and Research

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
6368 FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: AUG 7 2002
FROM: Director
Division of OTC Drug Products, HFD-560
SUBJECT: Material for Docket No. 98N-0337
TO: Dockets Management Branch, HFA-305

- The attached material should be placed on public display under the above referenced Docket No.
- This material should be cross-referenced to Comment No. APP 42


Charles J. Ganley, M.D.

Attachment