



OCT 9 2002

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L N K International, Inc.  
Attention: Pankaj S. Chudgar, Vice President  
60 Arkay Drive  
Hauppauge, LI, New York 11788

RE: Docket No. 98N-0337  
Application for Exemption  
APP 41

Dear Mr. Chudgar:

We are responding to your application for exemption (APP) 41, dated May 31, 2002, requesting a deferral of time for compliance with the Drug Facts labeling requirements in 21 CFR 201.66. You indicated that your company needs additional time until the end of 2002 or until the current inventory of labeling for 19 specifically identified OTC drug products is exhausted, whichever occurs first. You stated that these deferrals will enable your company to shift to a larger or alternative package style for these products to comply with the new labeling requirements. You also requested that the Agency review the proposed revised labeling for the 19 drug products included in the application.

You indicated that your company's deferral requests apply only to the specifically mentioned 19 products on hand that had been previously labeled with the intention of delivery prior to May 15, 2002. However, you stated that, due to unforeseen decline usage of these products, you have 4 months of product inventory that is already packaged and labeled for consumer use. You further stated that your company has destroyed all remaining non-compliant labels for these products and remains committed to changing over to the new compliant labeling on the next packaging of these products.

For the reasons provided in your application, the Agency is, as a matter of enforcement discretion, granting your company's request for a deferral from the "Drug Facts" labeling requirements in 21 CFR 201.66. We intend to exercise enforcement discretion for the 19 products identified in APP 41 until December 31, 2002. At the end of this deferral period, the labeling for all of these products must comply with the requirements of 21 CFR 201.66 at the time the products are initially introduced or initially delivered for introduction into interstate commerce in the United States.

The Agency points out that use of the heading "Questions or Comments" in the "Drug Facts" area is voluntary. The Agency has allotted space within the Drug Facts box or similar enclosure for a telephone number. While this labeling is not required, the Agency strongly encourages all manufacturers, distributors, and packers to include a telephone number and the days of the week and the time of the day when a person is available to respond to questions.

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Concerning your request that the Agency review each of the 19 draft labels included in your application, the Agency points out that although it routinely provides clarification of various features of the OTC labeling requirements, it does not assist in the drafting of a company's product labeling. The Agency recommends that if your company needs assistance in developing labeling to comply with 21 CFR 201.66, it should contact a private consultant for advice on how best to comply with the new labeling requirements.

We have conducted a cursory review of the "Drug Facts" portion only of your 19 draft labels and note several content and format features in the Drug Facts information that are not in compliance with 21 CFR 201.66. Rather than provide specific comments on each of these labels, we have the following general labeling comments to assist your company as it develops its new labeling for these 19 OTC drug products.

- Bulleted format is used to communicate information in the Drug Facts box or similar enclosure. Only information that specifically addresses the safe and effective use of the product is included under the Drug Facts information. All other information must not appear in this section of the label (21 CFR 201.66(d)(4)). For example, the draft Drug Facts labeling for the Walgreens' Antacid Tablets should not include the 5 lines beginning with "\*This product is not manufactured or distributed...". This information should appear outside the Drug Facts box or similar enclosure.
- Where appropriate, only the specifically designated headings and subheading set forth under 21 CFR 201.66(c)(1) through (c)(9) should appear in the Drug Fact box or similar enclosure. For example, the headings "Do not take" and "Do not take more than" are not included as specific subheadings under 21 CFR 201.66(c)(5)(ii) through (c)(5)(vii).
- Information under the heading "Directions" must appear in a bulleted format. A table format is required when dosage information is provided for three or more age groups (e.g., Aphedrid Tablets), or when the directions are complex (21 CFR 201.66(d)(9)).
- Required information about certain ingredients in OTC drug products (e.g., sodium) must appear in a specific format within the Drug Facts box or similar enclosure (21 CFR 201.66(c)(7)(i)). Also, the words "calcium and magnesium rich" and information about "a source of extra calcium" should not appear in the Drug Facts box or similar enclosure.
- Standard storage condition (i.e., room temperature) is considered to be 20°– 25° C (68°–77° F); data must be available to support a wider temperature range.
- The new labeling requirements limit the use of uppercase letters and bold type (21 CFR 201.66(d)(1)).
- Bulleted statements must be specifically aligned when using the standard or modified labeling format (21 CFR 201.66(d)(4) and 21 CFR 201.66(d)(10), respectively).

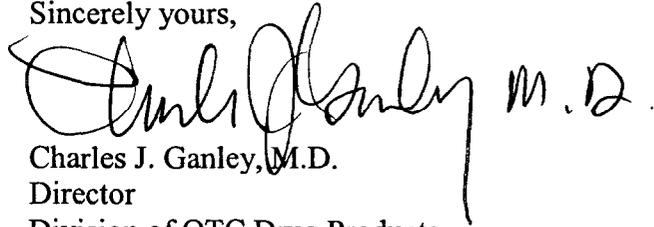
The Agency encourages your company to consider all other OTC format and content labeling requirements not mentioned above, particularly required labeling in an approved application or OTC drug monograph. The Agency also points out that it intends to publish in the near future an abbreviated new drug application (ANDA) labeling guidance containing recommendations on how reference listed drug (RLD) and ANDA holders can update their labeling consistent with the regulation on OTC drug product labeling. This guidance may be particularly helpful to your

company because several of the 19 products included in your application are ANDA ibuprofen tablets, which this labeling guidance will specifically address.

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.", written in a cursive style.

Charles J. Ganley, M.D.

Director

Division of OTC Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research

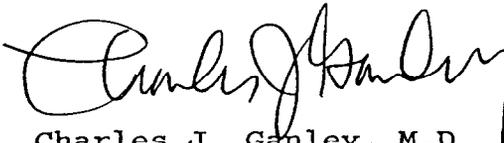
M E M O R A N D U M

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

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DATE: 10/9/02  
FROM: Director  
Division of OTC Drug Products, HFD-560  
SUBJECT: Material for Docket No. 98N0337  
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 41

  
Charles J. Ganley, M.D.

Attachment