018612_S022_Nicorette

020066_S004_Nicorette

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Approval Package for:

APPLICATION NUMBER:

18-612/S022
20-066/S004

Trade Name: Nicorette 2 mg and 4 mg Gum

Generic Name: Nicotine polacrilex

Sponsor: Hoechst Marion Roussel, Inc.

Approval Date: February 9, 1996

Indications: Provides for OTC marketing of Nicorette to adults only for the use in relief of nicotine withdrawal symptoms, as an aid to smoking cessation.

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APPLICATION NUMBER:

18-612/S022

20-066/S004

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Statistical Review(s)	
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APPLICATION NUMBER:

18-612/S022

20-066/S004

APPROVAL LETTER

FEB 9 1996

[redacted]
NDA 20-066/S-004

Hoechst Marion Roussel, Inc.
P.O. Box 9707
Kansas City, Missouri 64134-0707

Attention: M. Lorie Stewart
Assistant Director
U.S. Regulatory Affairs

Dear Ms. Stewart:

Please refer to your December 9, 1994, supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for Nicorette (nicotine polacrilex) 2 mg and 4 mg gum, respectively, in an over-the-counter environment.

We acknowledge receipt of your amendments dated December 20, 1994; January 30 and 31; February 3; March 1, 22 and 23; June 7; July 8; August 15 and 18; September 15; November 22; December 5, 11 and 15, 1995; February 6, 1996 and February 9, 1996.

The supplemental applications provide for over-the-counter (OTC) marketing of Nicorette to adults only (i.e. those who are at least 18 years of age) for use in relief of nicotine withdrawal symptoms, as an aid to smoking cessation.

We have completed the review of these supplemental applications, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use under the conditions set forth in the draft labeling submitted December 15, 1995, with the revisions listed below. Accordingly, the supplemental applications are approved effective on the date of this letter.

The labeling revisions are as follows:

1. The product cartons must bear the legend:

   Not for sale to those under 18 years of age.
   Proof of age required.
   Not for sale in vending machines or from any source where proof of age cannot be verified.

If the products were sold in vending machines, a consumer would not be able to determine in advance which product dose was appropriate.

2. The User's Guide and audiotape are considered part of the labeling for these products and must be revised to include the restriction stated above.

These revisions are terms of the supplemental NDA approval. Marketing the products before making the revisions, exactly as requested, in the products' final printed labeling (FPL) may render the products misbranded and unapproved new drugs.

Please submit sixteen copies of the FPL (blister label, starter pack, and non-starter pack cartons, and the User's Guide) to each application, as soon as it is available, but in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For the audiotape, please submit sixteen copies of the audiotape text in addition to two audiotapes. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved supplemental applications NDA 18-612/S-022 and NDA 20-066/S-004. Approval of this submission is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drugs become available, further revision of the labeling may be required.

We also remind you of your Phase 4 commitments specified in your submission dated February 6, 1996. These commitments are to:

1. Conduct an appropriate study of the safety and effectiveness of Nicorette (nicotine polacrilex) gum in adolescents as an aid to smoking cessation. We will assist you in determining study parameters and design. We expect to meet with you to discuss the study design within 6 months after approval.

2. Conduct a surveillance study designed to identify and report on sale to or use by people less than 18 years of age. This study will include:

   a. Media tracking, consumer tracking, proof of age surveillance, theft surveillance, and information derived from your marketing plan and smoking cessation program.
   b. A national/syndicated survey (PRIDE) conducted in conjunction with . ——— provided appropriate questions can be integrated into the survey. If an agreement with . ~— cannot be reached, FDA will be notified so that an alternative survey may be discussed.
   c. Survey of Drug Free Schools coordinators in response to an "outbreak" of misuse/abuse of Nicorette.

Quarterly summaries will be submitted to FDA. The surveillance study will continue for a period of three years, beginning with introduction of the products to the OTC market, at which time an integrated report will be submitted to FDA for review and evaluation to determine the need for continuation or change of all or parts. The surveillance study will continue during the evaluation.

Protocols, data, and final reports should be submitted to your INDs for these products and a copy of the cover letter sent to these NDAs. Should an IND not be required to meet your Phase 4 commitments, please submit protocols, data and final reports to these NDAs as correspondence. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 commitments."

Finally, we note and agree with your proposed marketing plan, described in your submission of February 6, 1996, which is designed to ensure compliance with the approved labeling. The plan includes the following elements:

a. Targeting any advertisement to adult smokers, making labeling available in Spanish by request, and featuring and reaching a variety of ethnic audiences.
b. "Trial size" or "sample" packs will not be offered.
c. Packaging of each gum piece in a child resistant blister.
d. Restriction of distribution to drugstores, mass merchandisers and supermarkets where other OTC drugs are sold. The products will not be distributed to other channels, including convenience stores or vending machines. Training of retailers will be provided regarding the marketing restrictions.
e. Offer of incentives to retailers to shelve Nicorette with other OTC drugs.
f. Availability of a free smoking cessation program (toll-free phone number on labeling).
g. If, through the surveillance program, violations of the conditions of sale are identified the retailer will be retrained to bring the store into compliance, or, distribution to the outlet in question will cease.

Please submit one market package of each drug when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mary I. Lambert, MN, RN, CS
Consumer Safety Officer
Telephone (301) 443-3741

Sincerely yours,

Paula Botstein MD 2/9/96

Paula Botstein, M.D.
Acting Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc: NDA 18-612/S-022
NDA 20-066/S-022
HF-2/MedWatch (with labeling)
HFD-2/MLumpkin
DISTRICT OFFICE
HFD-80 (with labeling)
HFD-103/OFFICE FILE (with labeling)
DIVISION FILE
HFD-170/MLambert
HFD-170/DKramer/MTheodorakis/TPermutt/HGeyer/CMoody/CWright
HFD-240 (with labeling)
HFD-613 (with labeling)
HFD-21/SPollitt/JTracey
HFD-735/DBarash (with labeling)
GCF-1/DFox
HF-22/WSchultz/CLorraine
HFD-312/KBudich
HFD-560/DBowen(with labeling)
HFD-105/MWeintraub

Drafted/MLambert/2/2/96
R/D By: CMoody/2/5/96
CWright/2/5/96
BCollier/2/7/96, 2/9/96
PBotstein/2/7/96, 2/9/96
WSchultz/2/8/96
CLorraine/2/8/96
DFox/2/8/96
F/T By: MLambert/2/9/96

APPROVAL