

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-958 / S-002

CORRESPONDENCE

CENTER FOR DRUG EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

FACSIMILE TRANSMISSION RECORD



DATE: October 23, 2001

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Message: Please refer to your supplemental new drug application NDA 20-958 S-002 dated July 06, 2001 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid Complete®.

In order to ensure a timely action for this supplemental new drug application, we request that you provide a commitment letter immediately. Please submit a letter of commitment for the following changes in labeling:

1. In the *Other information* section of the bottle labeling for all container sizes, the sponsor will revise the bulleted statements to be vertically aligned in accordance with 21 CFR 201.66(d)(4).
2. On the PDP of all the labeling, the SOI (i.e., "Acid Reducer +Antacid") be more prominently displayed in direct conjunction with the proprietary name in accordance with 201.61.
3. The sponsor will remove the "**NEW! BERRY** FLAVORED" statement after 180 days of marketing.

If you have any questions, please contact Daniel P. Keravich, M.S., M.B.A., Regulatory Project Manager, at 301-827-2248.

**APPEARS THIS WAY
ON ORIGINAL**