CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74517

ADMINISTRATIVE DOCUMENTS

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: **74-517** Date of Submission: **November 19, 1997**

Applicant's Name: **Eon Labs Manufacturing, Inc.**

Established Name: **Guanabenz Acetate Tablets USP, 4 mg and 8 mg**

Labeling Deficiencies:

1. GENERAL COMMENT

   As a result of the FDA Modernization Act of 1997, the statement "CAUTION: Federal law..." must be replaced with the symbol "Rx only" or "℞ only" throughout your labels and labeling. We refer you to the Guidance For Industry, "Implementation of Section 126, Elimination of Certain Labeling Requirements...", at the internet site: **http://www.fda.gov/cder/guidance/index.htm** for guidance. Please note that your container labels may be revised after approval.

2. INSERT

   a. DESCRIPTION

      Revise the last sentence to read:

      Guanabenz acetate tablets, for oral administration, contain 4 mg or 8 mg guanabenz (base).

   b. PRECAUTIONS

      Carcinogenesis, Mutagenesis, Impairment of Fertility

      i. Fourth sentence - "MRHDD" rather than "MHRDD".

      ii. Fifth sentence - "In the..." begins a new paragraph.

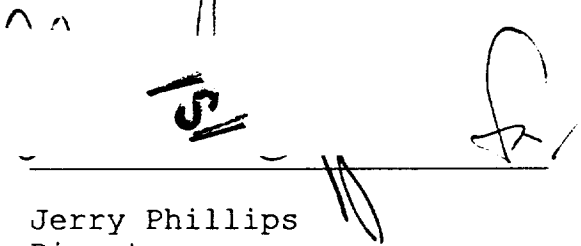
c. HOW SUPPLIED

i. See GENERAL COMMENT

ii. 4 mg (guanabenz base), round ...
8 mg (guanabenz base), round ...

Please revise your insert labeling, as instructed above, and submit final printed insert labeling.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.



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