CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75588

ADMINISTRATIVE DOCUMENTS

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

ANDA Number: 75-588 Date of Submission: February 19, 1999 & May 21, 1999

Applicant's Name: Pharmaceutical Formulations, Inc.

Established Name: Ibuprofen & Pseudoephedrine HCL Tablets USP, 200 mg/30 mg.

Labeling Deficiencies:

1. GENERAL COMMENTS

   The use of ibuprofen in your proposed proprietary name is unacceptable, since ibuprofen is a USAN (United States Adopted Name). 21 CFR 299.4(d) states that the Agency agrees with the "Guiding Principles for Coining United States Adopted Names for Drugs", which define a USAN as a nonproprietary name not subject to proprietary rights, but are entirely in the public domain.

2. CARTONS - (Oval capsule-shaped tablets and round tablets)

   Your proposed labeling does not meet the requirements of 21 CFR 201.66 [format and content requirements for over-the-counter (OTC) drug product labeling]. Since the most recently approved labeling of the reference listed drug does **not** utilize the new Drug Facts format, revise your labeling to be in accordance with the most recently approved labeling for Advil® Cold & Sinus.

3. UNIT-DOSE-BLISTERS – (Oval capsule-shaped tablets and round tablets)

   Satisfactory in final print as of February 19, 1999 submission.

Please revise your labels and labeling, as instructed above, and submit in final print or draft if you prefer.

Prior to approval, it may necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes-

http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with that of the reference listed drug with all differences annotated and explained.

/S/

Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

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

ANDA Number: 75-588

Date of Submission: December 2, 1999 (Major Amendment) &
March 17, 2000

Applicant's Name: Pharmaceutical Formulations, Inc.

Established Name: Ibuprofen and Pseudoephedrine HCL Tablets USP, 200 mg/30 mg

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Labeling Deficiencies:

1. GENERAL COMMENTS
   a. After reviewing your proposed proprietary name, "Cold & Sinus", it was determined by the Agency that in all actuality, it is not a proprietary name under "Guiding Principles for Coining United States Adopted Names for Drugs". Although the RLD uses "Cold & Sinus" to describe their proprietary name, Advil, these general medical terms **cannot** solely be considered a proprietary name. Please revise and/or comment.

   b. Revise your labeling to be in accord with 21 CFR 201.61 (b) and (c) so that the statement of identity, which consists of the established name and the pharmacological category, are presented in bold face on the principal display panel and shall be in a size reasonably related to the most prominent printed matter on such panel.

   c. To meet both the requirement for use of the established name and the need to easily identify the intended product without undue repitition, we suggest the following as the established name:

      Ibuprofen 200 mg
      and
      Pseudoephedrine HCL 30 mg
      Tablets

      Please note that the milligram amounts of ibuprofen and pseudoephedrine hydrochloride would appear in colored boxes so as not to be a part of the established name, yet be positioned such that the drug component is easily identifiable to the appropriate strength. If the colored box format is not possible, we would accept the following format for the product title:

      Ibuprofen and
      Pseudoephedrine HCL
      Tablets
      200 mg/30 mg

   d. Your proposed labeling does **not** meet the requirements of 21 CFR 201.66 [format and content requirements for over-the-counter (OTC) drug product labeling.] Since the most recently approved labeling of the reference listed drug does **not** utilize the new Drug Facts format, revise your labeling to be in accordance with the most recently approved labeling for Advil® Cold & Sinus.

2. CARTONS - (Oval capsule-shaped tablets and round tablets)
   See GENERAL COMMENTS above

3. PATIENT INFORMATION LEAFLET
   See GENERAL COMMENTS above

4. UNIT-DOSE-BLISTERS – (Oval capsule-shaped tablets and round tablets)
   Satisfactory in **final print** as of February 19, 1999 submission.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes- http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

/S/

Wm. Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

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

ANDA Number:	75-588
Date of Submission:	October 3, 2000
Applicant's Name:	Pharmaceutical Formulations, Inc.
Established Name:	Ibuprofen and Pseudoephedrine HCL Tablets USP, 200 mg/30 mg

Labeling Deficiencies:

1. GENERAL COMMENTS
   Revise your labeling to be in accord with 21 CFR 201.61 (b) and (c) so that the statement of identity, which consists of the established name and the pharmacological category, are presented in bold face on the principal display panel and shall be in a size reasonably related to the most prominent printed matter on such panel. Any reference to "Cold and Sinus Relief Formula" should be removed from the labels and labeling text, as it is considered to be a proprietary name by the Agency, unless you wish us to review it as such.

2. CARTONS - (Oval capsule-shaped tablets and round tablets)
   See GENERAL COMMENTS above

3. PATIENT INFORMATION LEAFLET
   See GENERAL COMMENTS above

4. UNIT-DOSE-BLISTERS – (Oval capsule-shaped tablets and round tablets)
   Satisfactory in **final print** as of February 19, 1999 submission.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes- http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

/S/

Wm. Peter Rickman
Acting Director
Division of Labeling and Program Support
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CORRESPONDENCE