OFFICE OF NEW DRUGS

NDAs: Foreign Language Labeling

CONTENTS

PURPOSE

- This MAPP outlines the policies and procedures to be followed in the Center for Drug Evaluation and Research (CDER) when applicants submitting new drug applications (NDAs) or supplemental applications request distribution of drug products within the United States and/or its Territories with labels and/or labeling in a foreign language.

BACKGROUND

- The regulations at 21 CFR 201.15(c)(1) require that "[a]ll words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English."

  Therefore, drug products with labels and/or labeling solely in a foreign language may be distributed in Puerto Rico and in some U.S. Territories, but not in the 50 States or the District of Columbia. Otherwise, if **any** information is provided in a foreign language in the label or labeling, then **all** information required by the Food, Drug, and Cosmetic Act (the Act) and regulations must be provided in the foreign language as well as in English in **both** the label and the labeling (21 CFR 201.15(c)(2) and (c)(3)).

  21 CFR 201.15 applies to both prescription and over-the-counter drug products.

- Dual-language (English and a foreign language) labeling may be marketed anywhere in the United States and its territories.

- 21 CFR 201.16 provides a specific Spanish-language version of certain required statements.

DEFINITIONS

- **Foreign language:** Any language other than English.
- **Label:** The written, printed, or graphic material either on the immediate container or on the outside container or wrapper.
- **Labeling:** All labels, package inserts, and other written, printed, or graphic material either on a product or its containers, or accompanying the product.

POLICY

- When applicants distribute foreign-language versions of currently approved labels and labeling, they are responsible for ensuring that such labels and labeling are complete and accurate.
- Labeling supplements for such foreign-language labels and labeling are not required and will not be accepted.
- FDA will not review foreign-language versions of labeling.
- Applicants desiring to market drug products with foreign-language labels and labeling will be asked to certify that such labels and labeling are complete and accurate translations of the current approved labels and labeling.

RESPONSIBILITIES AND PROCEDURES

The Project Management Staff will:

- Upon receipt of a supplement providing for foreign language labeling, notify the applicant that a supplement is not required and the submission will not be processed as a supplement.
- Notify the applicant that all foreign-language labeling should be submitted in the annual report along with a certification that it is a complete and accurate translation of the current labeling.
- Upon receipt of an annual report, check for foreign-language labeling. If present, verify that the annual report includes a certification that the foreign-language labeling is a complete and accurate translation of the current labels and labeling. The certification should include the dates of submission and, if appropriate, approval of the reference English labeling, or the date of submission if the labeling was submitted as a changes-being-effected supplement; or the date of the labeling if editorial changes have been made to the most recently approved labeling.

EFFECTIVE DATE

This MAPP is effective upon date of publication.