POLICY AND PROCEDURES

OFFICE OF NEW DRUGS

Foreign Language Labeling

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PURPOSE

- This MAPP outlines the policies and procedures for Center for Drug Evaluation and Research (CDER) staff when applicants submit new drug applications, biologics license applications, abbreviated new drug applications, or supplemental applications that contain labels and/or labeling in a foreign language intended for distribution in the United States and/or its Territories.

- This MAPP pertains to the following types of labeling: labels, prescribing information (also called package insert), patient package inserts, instructions for use, and Medication Guides.

BACKGROUND

- The regulations under 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."

- 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.

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

- If the drug product with dual-language labeling will be distributed in the 50 States or the District of Columbia, then all information required by the Federal Food, Drug, and Cosmetic 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)). Providing a portion of the label (instead of the full label or labeling) either in English or the foreign language is not permitted.

- 21 CFR 201.15 applies to both prescription and nonprescription drug products.

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

- Annual reports for drug products with foreign-language labels and labeling must contain currently approved foreign-language labels and labeling and certified translations of the labeling.

POLICY

- CDER will not review foreign-language versions or translations of foreign-language versions of labeling.

PROCEDURES

- If foreign language labeling is incorrectly submitted as a supplement, the project management staff should notify the applicant that a supplement is not required and the submission will not be processed or reviewed as a supplement. The project management staff also should notify the applicant that all foreign-language labeling should be submitted in the annual report instead, along with a certification that it is a complete and accurate translation of the current labeling.

REFERENCES

1. 21 CFR 201.15
2. 21 CFR 201.16

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 and other written, printed, or graphic material either on a drug product or its containers, or accompanying the drug product.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
7/9/04	N/A	N/A
10/27/14	Rev 1	Updates procedures