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CENTER FOR DRUG EVALUATION AND RESEARCH

# Guidance for Industry

*The FDA published Good Guidance Practices in February 1997.  
This guidance was developed and issued prior to that date.*

Additional copies are available from:  
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

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OCT 2 1995

Dear Sir or Madam:

The purpose of this letter from the Center for Drug Evaluation and Research (CDER) is to provide you with the plan that CDER is using to implement the new injectable product nomenclature that became official in the United States Pharmacopeia 23.

Between 1991 and 1994, the United States Pharmacopeial Convention, Inc. (USPC) published several Pharmacopeial Forum proposals concerning the revision of injectable product nomenclature contained in General Chapter <1> INJECTIONS. The intent of revising this nomenclature was to simplify drug titles as well as make them more meaningful. The revised nomenclature became official in the United States Pharmacopeia 23 (USP) on January 1, 1995.

Since the revised nomenclature will affect over 130 monograph titles, CDER and USPC agreed that it would be unreasonable to expect manufacturers to revise all the injectable drug titles by USP 23's official date of January 1, 1995. Also, concern was expressed that time should be allotted to inform health care providers of these changes. Hence, USPC announced in their September-October 1993 Pharmacopeial Forum a plan to extend the time frame for changing these drug titles.

CDER, in turn, has prepared the following implementation plan which it is providing to CDER reviewers, industry and FDA Field Offices.

#### IMPLEMENTATION PLAN:

For drug products which are the subject of an official USP monograph, a revised injection title (revised established name) should not be used until a USP Supplement, stating the revised monograph title, has been published. Firms should revise the labels and labeling to reflect the new title within 18 months of the effective date of the Supplement.

For drug products which are not the subject of an official USP monograph (including products under development) CDER recommends that to avoid confusion, firms should consider using USP's revised nomenclature. The nomenclature is as follows:

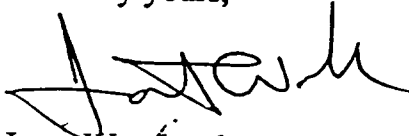
1. The term "STERILE" is eliminated from the titles of injectable products. [NOTE: The term "STERILE" will not be removed from appropriate monograph titles for WATER that are intended for parenteral use, such as *STERILE WATER FOR INJECTION*.]
2. For established names of injectable products, all of which are suitable for, and intended for parenteral administration, USP established the following criteria in determining the product's title:
  - a. LIQUIDS
    - (1) Title for liquid preparations that are drug substances or solutions thereof:  
[DRUG] INJECTION
    - (2) Title for liquid preparations of solids suspended in a suitable liquid medium:  
[DRUG] INJECTABLE SUSPENSION
    - (3) Title for liquid preparations of drug substances dissolved or dispersed in suitable emulsion medium:  
[DRUG] INJECTABLE EMULSION
  - b. SOLIDS
    - (1) Title for dry solids that, upon the addition of suitable vehicles, yield solutions conforming in all respects to the requirements for *Injections*:  
[DRUG] FOR INJECTION
    - (2) Title for dry solids that, upon the addition of suitable vehicles, yield preparations conforming in all respects to the requirements for *Injectable Suspensions*:  
[DRUG] FOR INJECTABLE SUSPENSION

Since the labels and labeling are being revised to comply with compendial requirements [21 CFR 314.70(d)], revised labels and labeling for approved drug products may be submitted with an annual report provided the change is described. However, if the firm prefers to submit revised labels and labeling as a "Special Supplement - Changes Being Effected" [21 CFR 314.70 (c)], this type of submission would be accepted since it affords the Agency an opportunity to approve the new labeling.

A "flag" or reminder statement should appear on the labels for a six month period alerting practitioners to the changes. This should assist practitioners in becoming familiar with these revised titles. An example of a "flag" would be: "FORMERLY STERILE (insert drug name)".

The Center for Drug Evaluation and Research appreciates your consideration of the implementation plan described in this letter. Questions or comments regarding this plan, should be directed to Compendial Operations Branch at (301) 594-0104.

Sincerely yours,



Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research