REVIEW MANAGEMENT

EXTRANEOUS REFERENCES IN PRODUCT LABELING: EXCLUSION OF AMERICAN HOSPITAL FORMULARY SERVICE (AHFS) PHARMACOLOGIC- THERAPEUTIC CLASSIFICATIONS

CONTENTS

PURPOSE

- To establish policy within the Center for Drug Evaluation and Research (CDER) regarding extraneous references to American Hospital Formulary Service (AHFS) classification system numbers in product labeling.

BACKGROUND

- The AHFS Drug Information contains drug monographs primarily for single-drug entities but also includes some monographs for drug combinations. The monographs include information on chemistry and stability, dosage and administration, cautions, drug interactions, and uses, approved, as well as unapproved.

- The AHFS Drug Information uses a classification system, the Pharmacologic-Therapeutic Classification System, to group the monographs. This system groups drug products into major classes based on drugs' pharmacologic-therapeutic actions. Where appropriate, a major class may then be further divided into subclasses. A unique number is assigned to each major class, with increments of that number assigned to its subclasses. Here is an example of this system:

  56:00 GASTROINTESTINAL DRUGS (major class)
  56:20 Emetics (subclass).

REFERENCES

- AHFS Drug Information, Bethesda, MD, American Society of Hospital Pharmacists, Inc.

- Federal Food, Drug and Cosmetic Act, Title 21, Part 201, Subpart B (21 CFR 201.57(m)) and Part 314, Subpart B (21 CFR 314.70(d)(3) and 314.81(b)(2)(iii)).

DEFINITIONS

- **Labeling**. To avoid any confusion about this term in this document, "labeling" means all labels and other written, printed or graphic matter upon any article. [Refer to Federal Food, Drug and Cosmetic Act, Section 201(m)].

POLICY

- The AHFS classifications make reference to information concerning drug use not in compliance with approved product labeling. The Center believes that reference to such unapproved uses in product labeling or sponsor promotional activities is inconsistent with current labeling regulations. Therefore, the Center should not approve labeling containing extraneous references to the AHFS classification number.

- CDER does not believe the AHFS drug information referenced by AHFS classification numbers is in compliance with 21 CFR 201.57(m). Therefore, any reference to an AHFS classification number outside that allowed by 21 CFR 201.57(m) should not be permitted.

PROCEDURES

- Divisions responsible for the oversight of products that presently have such references should notify sponsors of this CDER policy, and request removal of such extraneous references from their labeling at the time of next printing. This removal can be accomplished by regulation under 21 CFR 314.70(d)(3), "Changes described in the annual report" and 314.81(b)(2)(iii), "Other postmarketing reports - Annual report - Labeling."

- Divisions should not permit extraneous references to the AHFS classification number that may appear in pending product labeling and related promotional activities.

EFFECTIVE DATE

- This guide is effective upon date of publication.