Food and Drug Administration
Dockets Management Branch

PETITION 3 6 APR 11 P2:06

(Date) **April 6, 2006**

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 1-23, 12420 Parklawn Dr., Rockville, MD 20857. CITIZEN PETITION The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to recommend changes to NIST Handbook 44 (through the NIST and NCWM), and to the U.S. Pharmacopeia to reflect the required pharmacy quality control practices as presented in FDA reply SOO3Q-0531 in response to Docket No. 2003P-0531, namely "To ensure that there is a reliable value for dose unit weight, pharmacies using pill weight for dispensing **must,** either at the time of receipt of a drug product or dispensing, make a determination of average weight for the product".

A. ACTION REQUESTED

Issue recommendations to: a.) the NIST, the NCWM, and the U.S. Pharmacopeia asking them, in accordance with reply SOO3Q-0531, to prohibit the storing of pre-loaded (factory) databases in individual Prescription Scales, and the use of a common shared database, pre-loaded or otherwise, in the case of scales which are linked to a server and receive their average piece weight information over a network, and b.) the U.S. Pharmacopeia asking that the required pharmacy quality control practice presented in the FDA reply be included in the section of the U.S. Pharmacopeia relating to Prescription Scales.

B. STATEMENT OF GROUNDS

NIST Handbook 44 was modified on January 1, 2004 and now allows for the use of Prescription Scales with a pill counting feature to count pills by weight. Most Prescription Scales that count by weight rely on having a table of accurate average pill weights, cross referenced to NDC Codes, stored in electronic memory. It should be noted that those scales that do not store the average weight for future use must establish the average pill weight at the time of dispensing, and, therefore, are in compliance with the requirement contained in the FDA reply, and are not the subject of this petition.

Since the pill manufacturers do not publish pill weight this information must be gathered empirically. These scales are capable of empirically establishing the average weight of pills. The FDA reply indicates that this average weight must be updated at the time of receipt of a drug product or dispensing, thereby eliminating the counting problems posed by lot to lot weight tolerances, and reformulations. However, many Prescription Scales are shipped with factory loaded (or supplied) databases which contain average pill weights referenced by NDC Code. These weights must not be used in the pharmacy as they are not based upon the drug product as received by the pharmacy. This requirement must be followed, yet we cannot find a single regulatory document specifying this requirement.

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The NCWM, which can affect changes in NIST Handbook 44 (H44), had requested comments from the FDA prior to changing the longstanding Handbook 44 rule prohibiting counting anything by weight in commerce. NCWM and NIST have not, to the best of our knowledge, received any guidance on this matter directly from the FDA. Since the storage of average pill weight is a scale characteristic, and is specified as such, it properly comes under H44. The rules of H44 should be modified to reflect the FDA requirement and indicate that the stored average piece weight data can only be derived from drug product as received by the pharmacy. Scales must not have stored average weight data intended for long term use. H44 also has a section on Markings for scales. A marking on the face of the scale notifying the pharmacy of the stored average weight requirement would protect the public and facilitate proper use of the scale.

The section of the U.S. Pharmacopeia relating to Prescription Scales should be updated to include the pharmacy requirement for updating average drug piece weight as drug products are received or dispensed. The FDA should use its good offices to make Pharmacopeia personnel aware of this requirement.

In summation, the grounds upon which we find it necessary to ask the FDA to issue these very important recommendations are: a) the "must" requirement for the pharmacy to make a determination of average weight for a drug product either at the time of receipt or dispensing is from an FDA reply to a petition, and b.) only the FDA has the information required to make this judgment, and c.) the FDA is a highly respected regulatory agency whose recommendations concerning a matter of public interest and safety will be heeded when received directly from the FDA.

C. ENVIRONMENTAL IMPACT STATEMENT

We seek Categorical Exclusion per Sec. 25.30 General, Subparagraph (a). This is an administrative action and has no environmental impact.

D. ECONOMIC IMPACT STATEMENT

We will submit upon request.

E. CERTIFICATION
The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

James Q. Maloy (Signature)

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