Food and Drug Administration
Dockets Management Branch

PETITION

(Date) **November 14, 2003**

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 Issue **a report to the NIST, the NCWM, and the Petitioner, providing the necessary information, available only to the FDA, on pill weight tolerances and/or variations caused by reformulations, in order to allow a proper evaluation of the danger to the public posed by pending changes to NIST Handbook 44 which would allow the dispensing of pills based upon weight rather than count in pharmacies.**

A. ACTION REQUESTED

Issue a report specifying the typical range of batch to batch and single batch tolerances on pill weights (excipient weight plus dosage weight), based upon information reported by manufacturers to the FDA. The report could summarize its findings in a table of pill weight total tolerances in percent versus pill weight range. The report might also contain information on predicted counting errors based upon batch to batch tolerances and single batch tolerances. The report need not relate to specific drugs or reveal any proprietary information.

B. STATEMENT OF GROUNDS

The pending approved change to NIST Handbook 44 (320-2 V S1.2.3 Table 6.3.b and UR.3.12), allows for the use of Prescription Scales with a pill counting feature to count pills by weight. This single exception to the long-standing exclusion of scales that count by weight in commerce was ratified by the NCWM in July, 2003. The main reason sited for the change was "there is a high level of regulatory oversight by the U.S. Food and Drug Administration (FDA) to ensure that prescription drug dosages are uniform, unlike other commodities sold by count based upon weight". The final paragraph of the proposed changes started "The Committee asks for input from the Food and Drug Administration", but no subsequent mention was made of any input from the FDA at the July, 2003 meeting.

Since FDA regulatory oversight of prescription drug dosage weight was sited as a main reason for passing the change, and the FDA was invited to present input, it is imperative that the FDA now respond with the requested necessary information to allow the NIST, and NCWM to reach a proper final decision, thereby protecting both the public and pharmacists from erroneous pill counts in filling prescriptions.

While it is true that the dosage weight of pills is controlled, it is not controlled at a level that would permit using pill weight as the controlling factor for counting

pills. In the U.S. Pharmacopeia, in the section relating to uniformity of dosage (Section 905, USP 24-NF 19 Supplement, July1, 2000, pages 2094 to 2096), we find that dosage weight tolerances of +/_ 15% are allowed for drugs. This totally controverts the assumption made by the NCWM in changing NIST Handbook 44 to permit the counting of pills based upon weight.

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. Since the pill manufacturers do not publish pill weight this information must be gathered empirically. The scales are capable of establishing the average weight of a sample of pills. However, based upon the fact that a Relative Standard Deviation of 6% is allowable, for a sample of 30 pills (per USP), the stored average piece weight could hardly be called accurate. This high tolerance should not be acceptable for counting pills in commerce.

Additionally, to further complicate the matter, reformulation of pills is allowed whereby the weight of the excipients changes but the weight of the active ingredient remains the same, and the same NDC code is used for both the old and the reformulated versions (same drug efficacy). Ergo, two versions of the same drug, with the same NDC Code, but two quite different pill weights, are in the marketplace at the same time.

The only proper argument in favor of counting pills by weight is that it can save the Pharmacist time in filling larger prescriptions. This argument becomes greatly diminished if the Pharmacist must recalibrate the scale for average pill weight with every new supply bottle (which would at least put tolerances in the Relative Standard Deviation class).

The argument has been presented that counting by weight is more accurate than counting by hand. Studies have shown that counting by hand produced an error rate of about 0.4%, which is significantly lower than the error rate the +/- 15% tolerance allowable under the USP criteria would produce. The FDA can provide data on predicted error rates using actual pill weight data provided to the FDA by pill manufacturers. This would provide valuable guidance in this matter.

In summation, the grounds upon which we ask the FDA to issue this very important report about unpublished characteristics of prescription drugs, some of which are controlled substances, is that only the FDA has the necessary data, furnished by manufacturers, to determine the actual single batch, and batch to batch, pill weight tolerances that pharmacists will encounter. This information will allow the NIST and NCWM to reach proper conclusions in this matter.

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)

James Q. Maloy Name of Petitioner

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