Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 420.200 Compendium Revisions and Deletions (CPG 7132.02)

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BACKGROUND:

The USP and NF are continually being revised to keep pace with advances in new drugs, analytical methods, changes in governmental regulations, etc. The revisions are put into effect through periodic publication of supplements and publication of new editions of the compendia every five years. The revisions may, among other things, add monographs for new drugs, delete monographs for others, change analytical procedures, or alter specific requirements affecting strength, quality, and purity of the article. The official article may be a drug product, an active ingredient, or a pharmaceutical necessity.

On 7/1/80, when the combined USP XX/NF XV became official a major change occurred. All monographs for dosage forms and active ingredients were placed in the USP whereas all monographs for pharmaceutical necessities were placed in the NF. It is anticipated that because of these changes that many more articles, transferred from one compendium to the other, will have to be relabeled than would normally be expected when a new compendium becomes official. However, our basic policy will remain unchanged.

POLICY:

1. Articles shipped prior to and after the official date of the current USP or NF.

A. All official articles shipped after the current USP/NF became official should be in compliance with the current compendia.

B. All official articles shipped prior to the date that the current USP/NF became official should be in compliance with the official compendia in effect at the time of shipment.

2. Articles that have been dropped from the USP or NF.

Articles which at one time or another were recognized in either the USP or NF, but are no longer recognized in the current edition of either compendium should, if they are labeled as conforming to a superseded USP or NF, bear a statement that the article is no longer official.

3. Articles that differ in strength, quality, or purity from the current USP or NF.

Under Section 501(b) of the Act, a drug defined in an official compendium shall not be deemed to be adulterated if it differs from the compendial standard of strength, quality, or purity if the difference is plainly stated on the label. 21 CFR 299.5(c) further clarifies this by requiring that the label statement show all the respects in which such drug so differs, and the extent of each such difference.

4. Articles that differ in identity from the USP or NF standard.

Both the USP and NF under "OFFICIAL" and "OFFICIAL ARTICLES" in the General Notices section specify that where a product fails to comply with the identity prescribed in the compendia, such product shall be designated by a name that is clearly distinguishing and differentiating from any name recognized in the compendia. This is also stated in 21 CFR 299.5(a).

REGULATORY ACTION GUIDANCE:

Regulatory action is not indicated based solely on the continued use of existing stocks of old labels bearing the old USP or NF designation provided that the firm makes arrangements to revise labels in a reasonable period of time, and the drug meets the monograph requirements of the current compendium.

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