



**Health and Human Services
Supply Service Center
Perry Point, MD 21902**



REQUEST FOR EXEMPTION FROM 21 CFR 201.66

Food and Drug Administration
Attention: Dockets Management Branch, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Dockets Manager:

Please refer to Title 21, Part 201, Subpart C, Section 201.66 titled "Format and Content Requirements for Over-The-Counter (OTC) Drug Products" and also to Federal Register Docket No. 98N-0337 which established a deadline for industry compliance with the new OTC labeling requirements.

The Department of Health and Human Services, Supply Service Center (HHS SSC) located at Perry Point, Maryland is positioned organizationally within the Office of the Assistant Secretary for Administration and Management's Program Support Center's Administrative Operations Service (AOS), Division of Supply Management. The HHS SSC serves the worldwide healthcare facilities of the various departments of the Federal Government as a source of pharmaceutical, medical and dental supplies. The HHS SSC is also the only FDA licensed pharmaceutical repackaging facility operated by the Federal Government that distributes products to several different federal agencies. As such, the HHS SSC provides unit-of-use pharmaceutical pre-packs to a variety of federal customers including the National Institutes of Health, St. Elizabeth's Hospital and the Department of Interior in the Washington DC metro area; the Indian Health Service, Department of Defense, Department of Veterans' Affairs, Department of Justice, and Department of Transportation throughout the fifty states; and the Peace Corps, State Department Embassies, U.S. Agency for International Development, and Pacific Basin healthcare facilities around the world.

The federal facilities that purchase the OTC medications repackaged by the HHS SSC dispense these medications only on receipt of a valid order from a licensed healthcare practitioner. Although available over-the-counter, these medications are dispensed to entitled patients under the same formulary guidelines as those medications restricted to prescription only.

In addition, during the dispensing process pharmacy prescription labels bearing specific practitioner information are affixed directly to the unit-of-use packages obscuring any information provided by our container labeling.

Based upon the circumstances under which these repackaged OTC medications are dispensed to entitled patients at federal healthcare facilities, we consider an exemption from 21 CFR 201.66 justified.

98N-0337

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If you have any questions, call William C. Koch, R.Ph., at (410) 642-2244 Ext. 219.

Sincerely,

A handwritten signature in black ink, appearing to read "Lorraine M. D'Angelo". The signature is fluid and cursive, with the first name being the most prominent.

Lorraine M. D'Angelo

Director

HHS Supply Service Center

Division of Supply Management

Administrative Operations Service

Program Support Center