Amendment to the June 4, 1993 Memorandum of Understanding
Between
The Food and Drug Administration, Public Health Service
Department of Health and Human Services
and
The Environmental Protection Agency

Amendment to Notice Regarding Matters of Mutual Responsibility - Regulation of Liquid Chemical Germicides Intended for Use on Medical Devices

I. PURPOSE

This amendment to the June 4, 1993 Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) revises the disclaimer statement required to appear on the labels of all liquid chemical germicides, other than sterilants that have received FDA premarket clearance or approval.

II. BACKGROUND

On June 4, 1993, a MOU was signed between FDA and EPA as an interim measure to abolishing dual regulation of liquid chemical germicides. Under the MOU liquid chemical germicides, considered to be medical devices, are divided into two product categories: (1) sterilants and (2) general purpose disinfectants. FDA has primary jurisdiction over germicides with sterilant claims. This jurisdiction includes sterilant products which also bear subordinate tuberculocidal or virucidal claims supporting their use pattern as a high level disinfectant. EPA has primary jurisdiction over the general purpose disinfectants. Under the MOU, both FDA and EPA are required to initiate rulemaking so as to give each Agency sole jurisdiction over its assigned category. Until the rulemakings take effect, the MOU sets forth interim procedures designed to ease any possible regulatory burden that was associated with the submission of duplicate data packages to the Agencies.

Among other things, the MOU specified label language to be placed on labels of certain liquid chemical germicides. For the reasons explained below, this amendment substitutes new language for that originally specified in the MOU.

III. AMENDMENT

A. Background

The existing label language specified in Paragraph IV(A)(5) of the MOU, which must appear on the labels of liquid chemical germicides other than sterilants that have received FDA premarketing clearance or approval, is:

"This product is not to be used on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body."

Since the MOU was signed, it has been brought to EPA's and FDA's attention that the present label disclaimer does not allow for the use of general purpose disinfectants as a precleaner for the removal of gross filth on medical devices prior to their sterilization. Included under the "DIRECTIONS FOR USE" on the label of sterilant products, is a statement requiring the thorough cleaning, rinsing, and drying of medical instruments and equipment prior to disinfection and sterilization. This amendment only serves to revise the disclaimer statement currently required on the labels of all liquid chemical germicides, other than sterilants. The revised label disclaimer statement will allow the use of general purpose disinfectants on medical devices, as a precleaner, prior to sterilization.

B. Amended Language

Paragraph IV(A)(5) of the June 4, 1993 Memorandum of Understanding between the Food and Drug Administration, Public Health Service, Department of Health and Human Services, and the Environmental Protection Agency is amended by striking the entire text of Paragraph IV(A)(5) and replacing it with the following:

As part of the EPA registration process, EPA will require registrants of liquid chemical germicides, other than sterilants that have received FDA premarketing clearance or approval, to put the following statement on their product labels:

"This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection."

IV. NAME AND ADDRESS OF PARTICIPATING PARTIES

A. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

B. Environmental Protection Agency
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V. LIAISON OFFICERS

A. For the Food and Drug Administration:
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VI. EFFECTIVE DATE of AMENDMENT

This amendment to the June 4, 1993 MOU becomes effective upon acceptance by both parties.

APPROVED AND ACCEPTED FOR THE ENVIRONMENTAL PROTECTION AGENCY

By: /SIGNED/
Daniel M. Barolo

Title: Director

Date: June 2, 1994

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By: /SIGNED/
Ronald M. Johnson

Title: Director

Date: June 20, 1994