NATIONAL ADMINISTRATIVE REGISTER · APRIL 22, 1992

AMENDMENT OF CATEGORIES OF DRUG PRODUCTS TO QUALIFY UNDER SPECIAL LANE

BFAD MEMORANDUM CIRCULAR NO. 6, April 22, 1992

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The BFAD found and has noted that:

1. BFAD Memorandum Circular No. 12 s. 1991 has sufficiently covered registered drug products whose manufacture is being transferred from one registered manufacturer to another which are allowed in the Special Lane provided for under M.C. No. 5 s. 1990 as Category G;

2. The need for the Category C of drug products allowed under the Special Lane may be served by the regular registration lane if illicit monopoly is sufficiently remedied by facilitating application for registration of drug products marketed by not more than five (5) establishments;

3. There is a remarkable increase in the application for registration under the Special Lane causing backlog even in the same special lane;

More efficient service in matters of registration of drug products may be served by reducing the number of products eligible for Special Lane;

4. M.C. No. 5 s. 1990 is a temporary measure to facilitate action on application for registration while the regular registration lane is still unable to meet the demand of registration for certain desired characteristics of drug products and is designed to be eventually phased out.

A. Therefore, Category G of drug products is deleted from among the products qualified under the Special Lane, so that application for registration of drug products undergoing a change of manufacturer who may not be qualified for a conditional CPR under MC 12 s. 1991 will be processed in the regular registration lane.

B. Further, Category C of M.C. No. 5 s. 1990 is hereby amended to read:

> "Products of drug establishments whose licenses to operate were issued or renewed after January 1989 and actually marketed locally by no more five (5) other drug establishments."

C. Furthermore, the accomplishment of information sheet in order to classify the application for Special Lane will no longer be required. Instead, during the pre-assessment of the application for registration, the BFAD evaluator will determine whether the same is eligible under Special Lane or not.

This rule shall be effective immediately upon approval by the Secretary of Health.

Adopted: 22 Apr. 1992

(SGD.) QUINTIN L. KINTANAR, M.D., PH.D., CESO I
Director

Approved:

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(SGD.) ANTONIO O. PERIQUET, M.D.
Secretary of Health

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