SUPPLEMENTAL POLICIES

STERILITY OF OPHTHALMIC PRODUCTS

In a statement of policy issued on September 1, 1964, the Food and Drug Administration ruled that liquid preparations offered or intended for ophthalmic use that are not sterile may be regarded as adulterated within the meaning of section 501(c) of the FFDCA, and, further, may be deemed misbranded within the meaning of section 502(j) of the Act. On October 28, 1972, this ruling was extended to affect all preparations for ophthalmic use.

1. Purpose:

   The purpose of this guide is to clarify the Center's position regarding the sterility of ophthalmic products.

2. Policy:

   a. It is the policy of the Center that, as presently stated, 21 CFR 200.50 pertains to all animal ophthalmics including powders and aerosols. Communications to drug sponsors should indicate this policy.

   b. The Center is pursuing the National Academy of Sciences/National Research Council recommendation that powders and aerosols should not be used in the eyes, since these dosage forms tend to produce foreign body reactions. The Center discourages development of ophthalmic products intended to be delivered as powders/aerosols. Applications utilizing these routes of administration will be considered on a case-by-case basis with safety data generated on each product.

   c. All animal ophthalmic products shall also have pyrogen levels within established limits.