



5-27-82

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: The Bionox Corporation
"BIONOX NO. 1"
EPA File Symbol 46506-R
Conference of May 27, 1982

Participants: Granville M. Moore, Bionox Corporation
Kyle Sibmovic, PhD, Litton Bionetics Medical Laboratories
Robert J. W. Kuray, Attorney, Bionox Corporation
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Purpose: To discuss the type of carrier modification for the AOAC
Sporicidal Test that would be appropriate for demonstrating
efficacy of the subject product, Bionox No. 1, as a surface
sterilizing agent for specified types of hard non-porous
surfaces such as unhinged instruments.

Conclusions: (1) Injection needles (about 1" long, 24 gauge) were suggested
as an acceptable substitute for the silk suture loop carrier
specified in the AOAC Sporocidal Test.

(2) If preliminary testing indicates that the injection needle
is a suitable carrier, data will be developed on 720
carriers, 360 injection needles and 360 porcelain peni-
cylinders, to fulfill the efficacy data requirements
specified in the DIS/TSS-9 enclosure for sterilizers.

(3) Further consultation will be required, if the injection
needle is not a satisfactory carrier.

(4) Omission of a titration analysis intended to be conducted
for the storage stability study does not negate the study
when the presence of chlorine in the product is indicated
in a subsequent analyses.

(5) Revised labeling will accompany the efficacy data. Claims
for sterilization will be restricted to the treatment of
precleaned unhinged instruments. Claims for the treatment
of precleaned food-contact surfaces will not be acceptable
at an antimicrobial level higher than the disinfectant
level of activity.

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