



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

1-12-83

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: The Bionox Corporation
"BIONOX NO. 1"
EPA File Symbol 46506-R
Conference of January 12, 1983

Participants: Tom Funderburk, President, Bionox Corporation
R. B. Laine, Vice President, Bionox Corporation
Kyle Sibmovic, PhD, Litton Bionetics Medical Laboratories
Dorothy M. Portner, TSS/DIS
Henrietta C. Lucke, PM 32/DIS

Purpose: To discuss problems associated with testing methodology to support sterilization claims and to propose changing claims for product efficacy from sterilization to disinfection.

Conclusions: (1) Injection needles, the carrier substitute suggested for the silk suture loop carrier at the conference of May 27, 1982, has proven to be unsatisfactory because the bore frequently plugs with media and causes positive results.

(2) Representation of this product for disinfecting rather than sterilization was proposed because:

(a) A spraying device to simultaneously dispense liquid sodium hypochlorite with equal parts [REDACTED]

(b) The use pattern for disinfecting precleaned food contact surfaces in the fish and poultry industries and the inanimate hospital area surfaces by spraying is a prime marketing area

(c) Basic data to support the product as a disinfectant can be generated readily.

(3) Upon submission of a proposed label for disinfection, developed in accordance with the DIS/TSS-15 enclosure, TSS will expeditiously indicate the appropriate protocol for developing the required data to support label efficacy claims and use patterns.

(4) Investigation for a suitable carrier to substitute for the injection needle in order to eventually represent this product for sterilization too will be pursued.

(5) [REDACTED]

INERT INGREDIENT AND COMMERCIAL/FINANCIAL INFORMATION ARE NOT INCLUDED