DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date JAN 15 1985

From Director
Division of OTC Drug Evaluation (HFN-210)

Subject Material for Docket No. 76N-052N

To Dockets Management Branch (HFA-305)

Attached are copies of the Environmental Assessment and Finding of No Significant Impact for the notice of proposed rulemaking on OTC nasal decongestant drug products that was published in the FEDERAL REGISTER of January 15, 1985 and has been assigned docket number 76N-052N.

William E. Gilbertson, Pharm. D.

76N-0052N

EA 1

Environmental Assessment for the
Notice of Proposed Rulemaking
for OTC Nasal Decongestant Drug Products

1. Description of the proposed rule. This proposed rule would establish conditions under which OTC nasal decongestant drug products for human use are generally recognized as safe and effective and not misbranded. This proposed rulemaking, if implemented as a final regulation, would cause reformulation of some OTC nasal decongestant drug products, revisions in labeling, and would allow the marketing of oxymetazoline hydrochloride and xylometazoline hydrochloride as OTC topical nasal decongestants. It would also permit pseudoephedrine hydrochloride and pseudoephedrine sulfate to be available as OTC oral nasal decongestants at dosage levels twice as high as those previously permitted for OTC use.

2. Introduction of substances into the environment. This proposal will not significantly affect the quantities and composition of substances entering the environment at the sites of production, use, and/or disposal of products affected by this proposed rulemaking.

3. Fate of emitted substances in the environment.

(a) There will be no significant effect on the air due to volatilization, photochemical and chemical degradation, rainout, or dispersion.

(b) There will be no significant effect on freshwater, estuarine, and marine ecosystems due to chemical and biodegradation; exchange between the water column and sediments via adsorption/desorption processes; accumulation in plant life, plankton, and fish through bioconcentration, excretion, and decomposition processes; introductions due to rainfall; or losses due to volatilization.

(c) There will be no significant effect on terrestrial ecosystems due to chemical and biodegradation, adsorption/desorption and leaching in soils, bioaccumulation in animal and plant life, inputs due to rainfall, or losses due to volatilization.

4. Effects on the environment of released substances. There will be no significant effect on the environment, which would be established by toxicological data, worst case analyses, or other appropriate methods to predict effects, including chronic and subchronic effects on humans and other

organisms and ecosystem-level effects in each of the environmental compartments listed in item 3, of substances that would be released in the environment as a consequence of this proposed rulemaking.

5. Utilization of natural resources and energy. There will be no significant effect on natural resources, including land use and energy to produce a given amount of any OTC drug product which is the subject of this proposed rulemaking, including the resources and energy used to dispose of wastes generated, as a consequence of the production, use, and/or disposal of the product.

6. Disruptions of the physical environment. There will be no significant effect on noise, odors, construction, or other disruptions associated directly or indirectly with this proposed rulemaking.

7. Mitigation measures. No measures are needed to avoid or mitigate potential adverse environmental effects associated with this proposed rulemaking.

8. Alternatives to the proposed rule. Because no potential adverse environmental effects have been identified for this proposed rulemaking, there is no need for an alternative to the proposal.

9. Certification. The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the agency responsible for preparation of the environmental assessment.

JAN 15 1985

Date

William E. Gilbertson, Pharm. D.
Director
Division of OTC Drug Evaluation
Office of Drug Standards
Center for Drugs and Biologics

Finding of No Significant Impact for the
Notice of Proposed Rulemaking for
OTC Nasal Decongestant Drug Products

The Director of the Division of OTC Drug Evaluation has carefully considered the potential environmental impacts of this proposed rule and has concluded that this proposal will not have a significant effect on the human environment and that an environmental impact statement therefore will not be prepared.

This proposed rule establishes conditions under which OTC nasal decongestant drug products for human use are generally recognized as safe and effective and not misbranded. If implemented as proposed, the final regulation would cause reformulation and revision in the labeling of some currently marketed products. This proposed rule would also allow the marketing of oxymetazoline hydrochloride and xylometazoline hydrochloride as OTC topical nasal decongestants, and it would permit pseudoephedrine hydrochloride and pseudoephedrine sulfate to be available as OTC oral nasal decongestants at dosage levels twice as high as those previously permitted for OTC use, but this change is not expected to significantly affect the environment. (See the attached Environmental Assessment.)

JAN 15 1985
Date

Wm E Gilbertson
William E. Gilbertson, Pharm. D.
Director
Division of OTC Drug Evaluation
Office of Drug Standards
Center for Drugs and Biologics