

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-448**

ENVIRONMENTAL ASSESSMENT and/or FONSI

~~REVIEW OF~~^Δ ENVIRONMENTAL ASSESSMENT

AND

FINDING OF NO SIGNIFICANT IMPACT

FOR

IMODIUM® A-D CHEWABLE TABLETS

(Loperamide Hydrochloride)

NDA 20-448

Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Gastrointestinal and Coagulation Drug Product

HFD-180

Food and Drug Administration

Center for Drug Evaluation and Research

Finding of No Significant Impact

NDA 20-448

Imodium® A-D Chewable Tablets
(Loperamide Hydrochloride)

The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental impact of their actions. FDA is required under NEPA to consider the environmental impact of approving certain drug product applications as an integral part of its regulatory process.

The Food and Drug Administration, Center for Drug Evaluation and Research has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

In support of their new drug application for Imodium A-D Chewable Tablets, McNeil Consumer Products Company has prepared an environmental assessment in accordance with 21 CFR 25.31a which evaluates the potential environmental impacts of the manufacture, use and disposal of the drug product.

Loperamide Hydrochloride is a synthetic drug that will be administered orally.

Disposal of the chemical substance may result from waste generated during packaging, returned, recalled, or expired goods and user disposal of empty or partly used product and packaging. Packaging waste, returned or unused market packages, recalled and expired goods will be sent to licensed incineration or landfilled facilities.

The Center for Drug Evaluation and Research has concluded that the product can be manufactured, used and disposed of without any expected adverse environmental effects. Adverse effects are not anticipated upon endangered or threatened species or upon

property listed in or eligible for listing in the National Register of Historic Places.

7/22/97

DATE

PREPARED BY:

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7/22/97

DATE

DIVISION CONCURRENCE:

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Chemistry Team Leader

7/24/97

DATE

CONCURRED: *0/*

Nancy B. Sager
Environmental Scientist
Center for Drug evaluation

Attachments

CC:

Original NDA 20-448/*B. Stoney*
HFD-357/FONSI File NDA 20-448
HFD-357/Docket File
HFD-205/FOI Copy
HFD-180/G.Chen

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