

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-923

ENVIRONMENTAL ASSESSMENT/FONSI

ENVIRONMENTAL ASSESSMENT

OPTIRAY-PHARMACY BULK PACK

**STATEMENT OF CATEGORICAL EXCLUSION FROM
THE REQUIREMENT FOR AN ENVIRONMENTAL ASSESSMENT**

DATE: September 3, 1997

SUBMITTED BY: Mallinckrodt Inc.
675 McDonnell Blvd.
P.O. Box 5840
St. Louis, MO 63134

PROPOSED ACTION:

Mallinckrodt is submitting an NDA for its Optiray-Pharmacy Bulk Package, including Optiray 350, 320 and 240 in 200 ml. bottles.

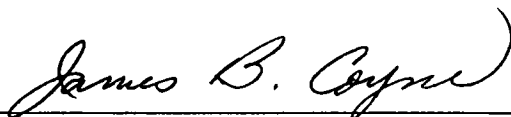
CLAIM OF EXCLUSION:

FDA regulations allow exclusions from the requirements for the preparation of environmental assessments for certain actions. Specifically, 21CFR25.31(a) allows this exclusion for "Action on an NDA,, if the action does not increase the use of the active moiety."

The proposed action is essentially an alternate labeling of an existing product and is not expected to increase the use of the active moiety. Therefore, the action should qualify for the exclusion.

CERTIFICATION:

The undersigned hereby certifies that the above information is true, accurate and complete, to the best of my knowledge, and the action, in my opinion, qualifies for the exclusion.



James B. Coyne
Environmental Program Manager