MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: AUG - 4 2003

FROM: Director

Division of OTC Drug Products (HFD-560)

SUBJECT: Public Administrative File for Laxative Drug Products for Over-the--Counter

Human Use; Proposed Amendment to the Tentative Final Monograph (1978N-

036L)

TO: Dockets Management Branch (HFA-305)

Under cover of this memorandum we are forwarding Volume No. 090TFM6 to be added to the public administrative file for the Tentative Final Monograph for Laxative Drug Products for Over-the-Counter Human Use. The references are cited in this TFM. References previously included in the Public Administrative File are not included with this memorandum. The attachments are to be placed on public display under Docket No. 1978N-036L.

If there are any questions, the contact person on my staff is Helen Cothran or Gerald M. Rachanow, at 301-827-2222.

Charles J. Ganley, M. D.

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