

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Linda Quinones
Dockets Management Branch, HFA-305

DATE: DEC 10 1980

FROM : Office of the Assistant Director for
Regulations Policy, HFK-70

SUBJECT: Docket #80P-0462CP, #80P-0443CP, #80P-0449CP, #78N-1227

Our staff reviewed three Citizens' Petitions listed above for trade secret and confidential commercial information.

The Belle de St. Claire November 7, 1980 petition for exemption from the Device GMP Regulation (Docket #80P-0462CP) is releasable with minor deletions. Enclosed is a purged copy of the document for display.

The Lloyd Hearing Aid Corp. October 13, 1980 petition for amendment to 21 CFR §801.420(a)(6) which defines "used hearing aid" (Docket #80P-0443CP) is releasable in its entirety.

The October 21, 1980 petition filed on behalf of the Amersham Corporation, Mallinckrodt, Inc., Medi-Physics, Inc. and New England Nuclear Corporation for certain modifications in nomenclature for radiopharmaceutical kits (Docket #80P-0449CP) is releasable in its entirety.

- The Braun Corporation September 18, 1980 petition for reconsideration on Medical Device Classification of Wheelchair Elevators (Docket #78N-1227) was not reviewed by our staff. FDA no longer reviews non-deficient petitions for confidential information.

Ronald A. Ross
for Susan E. Bounds

cc: HFK-132 (Abbott)
HFK-20

APPROPRIATE STAFF
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