Health Canada Santé Canada

Drugs Directorate
Tunney's Pasture
Address Locator # 0702A
OTTAWA, Ontario
K1A 0L2

May 29, 1996

LETTER SENT TO ASSOCIATIONS

Dear :

SUBJECT: *Filing of Supplemental New Drug Submissions, Supplemental Abbreviated New Drug Submissions, Notifiable Changes and Cross-Referenced New Drug Submissions*

The attached policy has been developed to provide for the filing of Supplemental New Drug Submissions, Supplemental Abbreviated New Drug Submissions, Notifiable Changes and Cross-Referenced Submissions in some circumstances prior to the issuance of the Notice of Compliance for the original submission.

The policy is effective immediately. If you have any questions or comments about the policy, please contact Marilyn Schwartz, A/Chief, Submission and Information Policy Division, 1620 Scott Street, Unit 14, A.L.: 3000E, Ottawa, Ontario K1A 0L2.

Dann M. Michols
Director General

Enclosure

Canada

May 10, 1996

POLICY ISSUES
from the Drugs Directorate

FILING OF SUPPLEMENTAL NEW DRUG SUBMISSIONS, SUPPLEMENTAL ABBREVIATED NEW DRUG SUBMISSIONS, NOTIFIABLE CHANGES AND CROSS-REFERENCED SUBMISSIONS

PURPOSE

To provide for the filing of Supplemental New Drug Submissions (SNDSs), Supplemental Abbreviated New Drug Submissions (SANDs), Notifiable Changes (NCs) and Cross Referenced Submissions (X-REF) prior to the issuance of the Notice of Compliance (NOC) for the original New Drug Submission (NDS) or Abbreviated New Drug Submission.

This policy applies only to those submissions not issued NOCs pending a scheduling decision or due to the Patented Medicines (Notice of Compliance) Regulations.

BACKGROUND

The Drugs Directorate has previously accepted SNDSs, SANDs, NCs and X-REF NDSs, ANDs, SNDSs and SANDSs only after the original NDS or ANDS has been issued a NOC.

However, a NOC might not be issued for the original submission for a significant length of time pending a scheduling decision or decisions related to the Patented Medicines (Notice of Compliance) Regulations.

During this time, additional information about the drug may become available, market dynamics may change, manufacturers' names may change or business alliances may be formed resulting in altered marketing conditions for the product.

FILING OF SUBMISSIONS

SNDSs, SANDs, NCs, and X-REF submissions will be accepted for review following the completion of the review of the original submission, but prior to the issuance of its NOC, for those submissions not issued NOCs pending a scheduling decision or due to the Patented Medicines (Notice of Compliance) Regulations.

The submissions will be reviewed in accordance with the Management of Drugs Submission Policy. NOCs for SNDSs and SANDs will be issued concurrently with the NOC for the original NDS/ANDS. Letters of No Objection to NCs will be sent to sponsors with the NOC for the original NDS/ANDS. NOCs for X-REF submissions will be issued concurrently with the NOC for the original NDS/ANDS.

PROCEDURES

Sponsors are requested to include in the covering letter for a SNDS, SANDs, NC or X-REF submission a reference to this policy if the submission is filed prior to the issuance of the NOC for the original submission.

These administrative procedures are in accordance with the Food and Drugs Act and Regulations.

All comments and concerns regarding this policy should be directed to the Submission and Information Policy Division, 1620 Scott Street, Unit 14, Address Locator: 3000E, Ottawa, Ontario K1A 0L2.