CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022312Orig1s000

ENVIRONMENTAL ASSESSMENT

APOTEX INC.
CANADA'S PHARMACEUTICAL COMPANY
SOCIÉTÉ PHARMACEUTIQUE ENTIÈREMENT CANADIENNE

REQUEST FOR EXCLUSION FROM REQUIREMENT FOR ENVIRONMENTAL IMPACT ASSESSMENT STATEMENT

Apotex Inc. claims categorical exclusion under 21 CFR 25.31(a) from filing an Environmental Impact Assessment Statement with respect to the production of the proposed dosage form of Docetaxel Injection, 40 mg/mL (20 mg/0.5 mL and 80 mg/2 mL) as outlined in this New Drug Application.

Under 21 CFR 25.31(a), a categorical exclusion exists for:

Action on an NDA if the action does not increase the use of the active moiety.

Apotex Inc. requests that, as specified by 21 CFR 25.31(a), the FDA take action by approving its application for Docetaxel Injection, 40 mg/mL (20 mg/0.5 mL and 80 mg/2 mL) which, as is stated more completely in section 1.12.12 of this application, will be administered at the same dosage level, for the same duration and for the same indications as the "listed" drug Taxotere® (docetaxel) Injection, 40 mg (base)/mL (sanofi-aventis U.S. LLC.). In addition, Apotex Inc. is unaware of any other data that would establish that its Docetaxel Injection, 40 mg/mL (20 mg/0.5 mL and 80 mg/2 mL) product may be toxic to organisms in the environment at expected levels of exposure.

Apotex Inc. also certifies that, to the best of its knowledge and in its opinion, it is in compliance with all federal, state, and local environmental protection requirements as these pertain to the manufacture of Docetaxel Injection, 40 mg/mL (20 mg/0.5 mL and 80 mg/2 mL) as described in this Abbreviated New Drug Application.

Bernice Tao
Director, Regulatory Affairs US

March 27, 2008
Date

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