

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-028

ENVIRONMENTAL ASSESSMENT



REQUEST FOR EXCLUSION FROM REQUIREMENT FOR ENVIRONMENTAL ASSESSMENT

Sandoz Canada Inc. hereby claims a categorical exclusion from the requirement of an Environmental Assessment, pursuant to § 25.31(a).

COSYNTROPIN INJECTION will be administered at the same dosage level, for the same duration and for the same indications as the "listed" drug, [RLD product name].

Sandoz Canada Inc. is requesting FDA to take action by approving its 505(b)(2) application for **COSYNTROPIN INJECTION**.

Sandoz Canada Inc. also certifies that, in its opinion, it is in compliance with the environmental protection requirements of Canada and the province of Quebec.

On the basis of the foregoing, Sandoz Canada Inc. submits that an Environmental Assessment is not required with this application and, therefore, requests that it be categorically excluded from the requirement to submit an Environmental Assessment.

Peggy Levy
Manager, Development Regulatory Centre

2005-12-19
Date