CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125294Orig1s000

ENVIRONMENTAL ASSESSMENT

STN 125294/0
Tbo-filgrastim

Environmental Assessment

A categorical exclusion is claimed for this BLA in accordance with 21 CFR part 25.31 (c) and (d). The environmental assessment is justified and acceptable as noted on the addendum to the primary CMC review dated September 23, 2010.

1.12.14 Environmental analysis

Justification for Absence of Environmental Risk Assessment for (b) (4)

The Environment Risk Assessment is not included in this BLA. The lack of an Environmental Risk Assessment for (b) (4) is justified by three reasons:

- According to 21 CFR Part 25 and FDA Guidance for Industry: Environment Assessment of Human Drug Biologics Applications, applications for marketing approval of a biologic product are excluded categorically, due to the products unlikely to result in significant risk to the environment.
- (b) (4) drug substance is a recombinant protein, which is very similar to naturally occurring human G-CSF. Therefore no potentially harmful effects to the environment are expected.
- (b) (4) is a comparable product of existing G-CSF on the market. The approval of the (b) (4) should not result in an increase of the total quantity released into the environment.

It is concluded that no Environmental Risk Assessment for (b) (4) is required.