CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-335/S-004

Chemistry Review(s)

CHEMIST'S REVIEW

1. ORGANIZATION	2. NDA NUMBER
HFD-150 DODP	21-335

3. NAME AND ADDRESS OF APPLICANT *(City and State)*

Novartis
One Health Plaza
East Hanover, NJ 07936-1080
Attention: Robert Miranda
Director, Drug Regulatory Affairs
Telephone: (973)-781-2282

4. AF NUMBER

5. SUPPLEMENT (S)
NUMBER(S) DATES(S)

6. NAME OF DRUG	7. NONPROPRIETARY NAME	SE1-004	28-Jun-02
Gleevec	imatinib mesylate		

8. SUPPLEMENT PROVIDES FOR:
a claim of categorical exclusion for an Environmental Assessment to support the use of Gleevec in the treatment of patients with Ph+ chronic myeloid leukemia (CML)

9. AMENDMENTS DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF
antineoplastic	RX X OTC ___	

13. DOSAGE FORM(S)	14. POTENCY
tablet	1 mg

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS
CURRENT YES___ NO___
REVIEWED YES___ NO___

17. COMMENTS

See page 2

cc:
NDA 21-335
HFD-150/Div. File
HFD-150/RWood
HFD-150/YAHsieh
HFD-150/AStaten
R/D Init. by:

18. CONCLUSIONS AND RECOMMENDATIONS

It is recommended that the request for a claim of categorical exclusion for an Environmental Assessment should be approved.

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Yung-Ao Hsieh, Ph.D.	/S/	27-Aug-02

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Summary of the Application

Gleevec (imatinib mesylate) is currently approved for the treatment of patients with Philadelphia positive (Ph+) chronic myeloid leukemia (CML) in blast crisis, accelerated phase or in chronic phase after failure of interferon-alpha treatment. This supplemental NDA application provides for the use of Gleevec as a first-line treatment of patients with Ph+ CML. A claim of categorical exclusion for an Environmental Assessment was submitted.

The applicant certifies that the expected level of imatinib mesylate introduced into the environment, as the result of the approval of this efficacy supplemental application and the previous approval, will not exceed a concentration of 1 ppb at the point of entry into the aquatic environment. Additionally, the applicant stated that to his knowledge, no extraordinary circumstances exist.

Conclusion and Recommendation

Adequate information has been presented to show that the requested approval of the efficacy supplement NDA 20-335 SE8-003 qualifies for a categorical exclusion from the requirement to prepare an EA under 21 CFR 25.31(b). It is recommended that the claim for a categorical exclusion for an EA should be approved.

/S/

Yung-Ao Hsieh, Ph.D.
Review Chemist, HFD-150

/S/

Rebecca H. Wood, Ph.D.
Chemistry Team Leader, HFD-150

cc:
NDA 21-335
HFD-150/Div. File
HFD-150/RHWood
HFD-150/YAHsieh
HFD-150/AStaten

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Yung-Ao Hsieh
8/27/02 08:25:56 AM
CHEMIST

Rebecca Wood
8/27/02 09:21:25 AM
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