CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-588/S-001
21-335/S-003

Chemistry Review(s)
**CHEMIST'S REVIEW**

1. **ORGANIZATION**
   - HFD-150 DODP
2. **NDA NUMBER**
   - 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. **AP NUMBER**

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

6. **NAME OF DRUG**
   - Gleevec

7. **NONPROPRIETARY NAME**
   - 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 pediatric patients with chronic myeloid leukemia (CML)

9. **AMENDMENTS DATES**
   - 28-Jun-02

10. **PHARMACOLOGICAL CATEGORY**
    - antineoplastic

11. **HOW DISPENSED**
    - RX X OTC ___

12. **RELATED IND/NDA/DMF**

13. **DOSED FORM(S)**
    - tablet

14. **POTENCY**
    - 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/AS Staten
    - 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**: Yung-Ao Hsieh, Ph.D.
    - **SIGNATURE**: [Signature]
    - **DATE COMPLETED**: 26-Aug-02

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/s/
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Yung-Ao Hsieh
8/27/02 08:17:20 AM
CHEMIST

Rebecca Wood
8/27/02 09:30:15 AM
CHEMIST