# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

**Application Number : 020707**

**Trade Name : SKELID TABLETS**

**Generic Name: Tiludronate Disodium 200mg Tablets**

**Sponsor : Sanofi Winthrop, Inc.**

**Approval Date: March 7, 1997**

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## APPLICATION 020707

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| | Included | Pending Completion | Not Prepared | Not Required |
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| **Approval Letter** | X | | | |
| **Tenative Approval Letter** | | | | |
| **Approvable Letter** | X | | | |
| **Final Printed Labeling** | | | | |
| **Medical Review(s)** | X | | | |
| **Chemistry Review(s)** | X | | | |
| **EA/FONSI** | X | | | |
| **Pharmacology Review(s)** | X | | | |
| **Statistical Review(s)** | X | | | |
| **Microbiology Review(s)** | | | | |
| **Clinical Pharmacology Biopharmaceutics Review(s)** | X | | | |
| **Bioequivalence Review(s)** | | | | |
| **Administrative Document(s)** | | | | |
| **Correspondence** | X | | | |
| **Patent Information** | X | | | |
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| **Exclusivity Summary** | X | | | |

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**Application Number 020707**

# APPROVAL LETTER

NDA 20-707

Sanofi Winthrop, Inc.
Attention: George Clay, Ph.D.
Great Valley Parkway
P.O. Box 3026
Malvern, PA 19355

Dear Dr. Clay:

Please refer to your new drug application dated February 28, 1996, received February 28, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Skelid, (tiludronate disodium) 200 mg Tablets.

We acknowledge receipt of your submissions dated April 17 and 18, June 7, 18, 24, and 28, July 1, August 8, September 10, 18, and 27, October 3, 17, 18, and 28(3), November 13 and 21(4), and December 4, 5, and 31, 1996; and January 7, 10, 21(2), 22, 29, and 31, and February 7(2) and 14, and March 6, 1997. The User Fee goal date for this application is September 7, 1997.

This new drug application provides for the treatment of Paget's disease of bone.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft package insert in the submission dated March 6, 1997 and blister and carton labeling submitted on February 7, 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on March 6, 1997. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-707. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-

up form, not final print. Please submit one copy to the Division of Metabolic and Endocrine Drug Products (HFD-510) and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Randy Hedin, R.Ph., Consumer Safety Officer, at (301) 443-3520.

Sincerely yours,

James Bilstad, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-707
HFD-510/Div. files
HFD-510/CSO/R.Hedin
HFD-510/SDutta/GTroendle/LBarbehenn/RSteigerwalt/SMarkofsky/SMoore
HFD-002/ORM (with labeling)
HFD-102/Office Director

# CENTER FOR DRUG EVALUATION AND RESEARCH

**Application Number 020707**

# APPROVABLE LETTER

NDA 20-707

FEB 28 1997

Sanofi Winthrop, Inc.
Attention: George A. Clay, Ph.D.
Vice President
Drug Regulatory Affairs
P.O. Box 3026
Malvern, PA 19355

Dear Dr. Clay:

Please refer to your new drug application dated February 28, 1996, received February 28, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Skelid, (tiludronate disodium) 200 mg Tablets.

We acknowledge receipt of your submissions dated April 17 and 18, June 7, 18, 24, and 28, July 1, August 8, September 10, 18, and 27, October 3, 17, 18, and 28(3), November 13 and 21(4), and December 4, 5, and 31, 1996; and January 7, 10, 21(2), 22, 29, and 31, and February 7(2) and 14, 1997. The User Fee goal date for this application is February 28, 1997.

We have completed the review of this application as submitted with draft labeling, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit draft labeling revised as discussed during the teleconference February 28, 1997. The draft labeling discussed during that teleconference is enclosed.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action, FDA may take action to withdraw the application.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, please contact Randy Hedin, R.Ph., Consumer Safety Officer, at (301) 443-3490.

Sincerely yours,

2/28/97

James Bilstad, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

cc:
Original NDA 20-707
HFD-510/Div. Files
HFD-002/ORM
HFD-92/DDM-DIAB
HFD-510/R.Hedin
HFD-510/SDutta/GTroendle/LBarbehenn/RSteigerwalt/SMarkofsky/SMoore
HFD-102/with labeling
HFD-101/L.Carter
DISTRICT OFFICE
HFD-40/DDMAC (with draft labeling)

Drafted by: MHess/2.28.97/N20-707.ae
Initialed by: LRipper/2.28.97
Final:

APPROVABLE (AE)