CSO NDA LABELING REVIEW OF PACKAGE INSERT

NDA: 20-388

DATE OF SUBMISSION: SLR-008, Geriatric Use, 8/24/99

DATE OF REVIEW: September 3, 1999

DRUG: Navelbine (vinorelbine tartrate) for Injection

SPONSOR: Glaxo Wellcome Inc.
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

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This submission provides for expansion of the PRECAUTIONS: Geriatric Use subsection, CLINICAL PHARMACOLOGY: Pharmacokinetics subsection, CLINICAL PHARMACOLOGY: Clinical Trials subsection, and ADVERSE REACTIONS: Hematologic subsection to provide additional information pertaining to geriatric patients in accordance with the Final Rule requiring a Geriatric Use subsection.

I checked the annual report (004) from April 1999 for any labeling changes. There were no changes. Then I compared the proposed draft labeling with the approved labeling from SLR-007 and have found no changes other than those indicated by the sponsor.

I sent a consult to Dr. Rahman, OCBP, since changes have been made to the Pharmacokinetics and Clinical Trials subsections of the Clinical Pharmacology section. The consult has a suspense date of November 30, 1999.

I suggest that the Medical Officer review the actual proposed changes to determine the validity and appropriateness of the claims.

/S/

/ 9-7-99

Maureen A. Pelosi
Project Manager

/S/

Concur:

Dotti Pease
Supervisor, Project Management Staff

/S/

Concur/Not Concur

Susan Honig, MD
Medical Officer

CC: Original NDA 20-388
HFD-150/Div File
/Honig
151/Pelosi

CSO NDA LABELING REVIEW OF PACKAGE INSERT

NDA: 20-388 / FA for SLR 008 and 009

DATE OF SUBMISSION: FA for SLR-008, July 10, 2000
SNC July 14, 2000

DATE OF REVIEW: August 3, 2000

DRUG: Navelbine (vinorelbine tartrate) Injection

SPONSOR: Glaxo Wellcome Inc.
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709

The submission was identified as FA for SLR-008. However, as I reviewed the changes I noticed that it incorporated the changes for SLR-009 as well. Hence, the sponsor submitted the July 14, 2000 SNC which stated that the FA also contained the changes for the CBE SLR-009.

This FA for SLR-008 provides for expansion of the PRECAUTIONS: Geriatric Use subsection, CLINICAL PHARMACOLOGY: Pharmacokinetics subsection, CLINICAL PHARMACOLOGY: Clinical Trials subsection, and ADVERSE REACTIONS: Hematologic subsection to provide additional information pertaining to geriatric patients in accordance with the Final Rule requiring a Geriatric Use subsection.

This FA for SLR-009 provides revisions to the CLINICAL PHARMACOLOGY, ADVERSE REACTIONS, PRECAUTIONS, AND WARNING sections of the package insert in response to our 8/6/99 facsimile.

I have reviewed the labeling, comparing it with the approved labeling from SLR-007, and draft labeling fron SLR 008 & 009 and have found it acceptable.

S /8-3-00
Maureen A. Pelosi
Regulatory Project Manager

S / 8- -00
Dotti Pease, SCSO

CC: Original NDA 20-388 / FA SLR-008 & 009
HFD-150/Div File
/Honig, Williams
151/Pelosi

CSO LABELING REVIEW
Attachment

11 pages redacted from this section of the approval package consisted of draft labeling

NDA 20-388 /S-008 and 009

Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

Attention: Marna Doucette
Product Director, Regulatory Affairs

Dear Ms. Doucette:

We acknowledge receipt of your July 10, 2000 submission containing final printed labeling in response to our May 12 and June 8, 2000 letters approving your new drug applications S-008 and S-009, respectively) for Navelbine (vinorelbine tartrate) Injection, 10 mg and 50 mg. We also acknowledge receipt of your July 14, 2000 correspondence informing us that the July 10, 2000 final printed labeling contains labeling for both supplements 008 and 009.

We have reviewed the labeling that you submitted in accordance with our approval letters, and we find it acceptable.

If you have any questions, contact Maureen A. Pelosi, Project Manager, at 301-594-5778.

Sincerely yours,

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

CC:
Archival NDA 20-388 (FA 008 & 009)
HFD-150/ Division File
HFD-150/ Pelosi (CSO)
Honig
Williams
Schmidt
Duan
Rahmana
Wood
Hsieh, YA
HF-2/Med Watch (with labeling)
HFD-92/DDMS (with labeling)
HFD-101/Carter (ADRA) (with labeling)
Office File (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
HFD-735/OP CC: Original NDA 20-896
HFD-735/OPDRA (with labeling)
DISTRICT OFFICE

Drafted by Pelosi 8-3-00
Initialed by Pease/8-7-00
Final by Pelosi/8-10-00

ACKNOWLEDGE AND RETAIN (AR)

Attachment: Labeling

11 pages redacted from this section of the approval package consisted of draft labeling