CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 017808/S014

Trade Name: MIACALCIN INJECTION

Generic Name: CALCITONIN SALMON

Sponsor: NOVARTIS PHARMACEUTICAL CORPORATION

Approval Date: 07/14/97

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 017808/S014

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Application Number: 017808/S014

APPROVAL LETTER

NDA 17-808/S-014

JUL 14 1997

Novartis Pharmaceutical Corporation
Attention: Mr. Jerry Klimek
Assistant Director, Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Dear Mr. Klimek:

Please refer to your supplemental new drug application dated March 19, 1997, received March 24, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.70(c) for Miacalcin (calcitonin salmon) Injection.

The supplemental application provides for a revision to the "Allergic Reactions" subsection of the WARNINGS section to read as follows:

> "For patients with suspected sensitivity to calcitonin, skin testing should be considered prior to treatment utilizing a dilute, sterile solution of Miacalcin (calcitonin-salmon) Injection, Synthetic. Physicians may wish to refer patients who require skin testing to an allergist. A detailed skin testing protocol is available from the Medical Services Department of Sandoz Pharmaceuticals Corporation."

We note that your submission proposed to implement this change immediately.

We have completed the review of this supplemental application and it is approved.

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,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 18-874
HFD-510/Div. files
HFD-510/CSO/R.Hedin
HFD-510/SDutta/GTroendle
DISTRICT OFFICE
HF-2/Medwatch (with labeling) + M.O.R.
HFD-92/DDM-DIAB (with labeling) + M.O.R.
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) + M.O.R.
HFI-20/Press Office (with labeling)

Drafted by: RH/June 13, 1997/N17808AP.LT5
Initialed by:RHédin
final: SDutta6.13/GTroendle6.16/EGalliers6.24.97

APPROVAL (AP)

APPEARS THIS WAY
ON ORIGINAL

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 017808/S014

CORRESPONDENCE

N... 17806 REF. N... 014
NDA SUPPL FOR SLR

ORIGINAL

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

NOVARTIS

March 19, 1997

Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products/HFD-510
Office of Drug Evaluation II
Attn: Document Control Room 14B-04
Center for Drug Evaluation
and Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA No. 17-808
MIACALCIN® (calcitonin salmon) INJECTION, SYNTHETIC

NDA No. 20-313
MIACALCIN® (calcitonin salmon) NASAL SPRAY

"SPECIAL SUPPLEMENT CHANGES BEING EFFECTED"

Dear Dr. Sobel:

Reference is made to our General Correspondence dated October 31, 1996 and to a telephone conversation with Mr. Randy Hedin on February 6, 1997 with regard to current labeling for Miacalcin® (calcitonin-salmon) Injection and Nasal Spray for the WARNINGS, Allergic Reactions subsection.

We are submitting 15 copies of revised labeling for Miacalcin® Injection and Nasal Spray with regard to the WARNINGS, Allergic Reactions subsection where the second paragraph now reads:

> "For patients with suspected sensitivity to calcitonin, skin testing should be considered prior to treatment utilizing a dilute, sterile solution of Miacalcin (calcitonin-salmon) Injection, Synthetic. Physicians may wish to refer patients who require skin testing to an allergist. A detailed skin testing protocol is available from the Medical Services Department of Sandoz Pharmaceuticals Corporation."

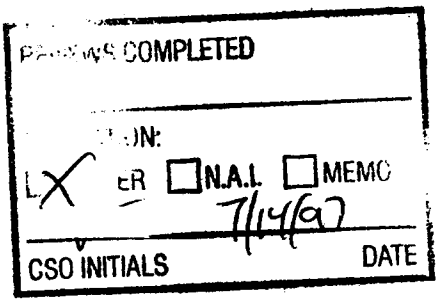
We have additionally revised the labeling for Miacalcin® (calcitonin salmon) Nasal Spray with regard to the second sentence of the first paragraph under the WARNINGS, Allergic Reactions subsection because of a few reported allergic-type reactions and one case of anaphylactic shock which appears to have been due to the preservative (see attached reports). Therefore, the second sentence of the first paragraph now reads:

> "A few cases of allergic-type reactions have been reported in patients receiving Miacalcin® (calcitonin salmon) Nasal Spray, including one case of anaphylactic shock, which appears to have been due to the preservative because the patient could tolerate injectable calcitonin-salmon without incident."

We intend to implement these changes immediately.

4/1/97

If there are any questions or concerns with this submission, please contact me at 201-503-8145.



Sincerely,

Jerry Klimek
Assistant Director,
Drug Regulatory Affairs

Attachments:
15 copies of Miacalcin® (calcitonin salmon) Injection, Synthetic package insert number 30167403
15 copies of Miacalcin® (calcitonin salmon) Nasal Spray package insert number 30367904
Adverse Event Reports for USA/96/01563/MIA, USA/96/00946/MIAC, and MIA/312/03001

APPEARS THIS WAY
ON ORIGINAL