



OCT - 3 2001

WARNING LETTER

Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jacob J. Beckel, R.Ph.
Chief Executive Officer
Custom Care Pharmacy
6206 Benjamin Road
Suite 311
Tampa, FL 33634

Dear Mr. Beckel:

We have received information that indicates that Custom Care Pharmacy is compounding Strontium Chloride, SR-89.

Your website indicates that your firm compounds Strontium Chloride, SR-89 in a strength of 4 mCi/vial. In our July 25, 2000, letter, we set forth the Agency's enforcement policy regarding the compounding of radiopharmaceuticals, including the compounding of drug products that are essentially generic copies of commercially available drug products.

Consistent with that enforcement policy, documentation is necessary substantiating that your compounded Strontium Chloride, SR-89, 4 mCi/vial, is different from the commercially available product, Metastron, 4 mCi/vial. In the absence of this documentation, the preparation of Strontium Chloride, SR-89 is not considered to be the traditional practice of pharmacy and violates the Federal Food, Drug, and Cosmetic Act (the Act) in that Strontium is a new drug within the meaning of section 201(p) and subject to the provisions of section 505 of the Act. No approval of an application filed pursuant to section 505 is in effect and no investigational new drug (IND) application under section 505(i) is on file for it. The continued marketing of Strontium Chloride, SR-89 without an approved new drug application constitutes a violation of section 505.

Strontium Chloride, SR-89, is also misbranded within the meaning of 502 (f)(1) of the Act, in that its labeling fails to bear adequate directions for the use for which it is being offered and it is not exempt from this requirement under regulation 21 C.F.R. 201.115 since it is an unapproved new drug.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that *all* your drug products are in compliance with federal laws and regulations. Failure to promptly correct all violations and prevent future violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step being taken to prevent the recurrence of the violations. Please provide us with information describing how your compounded Strontium Chloride, SR-89 product is different from the commercially available product, Metastron, 4 mCi/vial. Please also provide us with documentation that demonstrates that the Strontium Chloride, SR-89 product compounded by your firm provides a significant medical difference, for particular, identified patients receiving such product, as determined by the prescribing practitioners, compared with the commercially available Strontium Chloride, SR-89 product.

Please send the information and documentation outlined above to George R. Scott, Regulatory Operations Officer, Center for Drug Evaluation and Research, Office of Compliance, Division of Prescription Drug Compliance and Surveillance, 7520 Standish Place, Room 200, HFD-330, Rockville, Maryland 20855.

Sincerely,



Lana Ogram, Director
Division of Prescription Drug
Compliance and Surveillance