CPG Sec. 625.500 Failure to Register *and/or Drug List*

REGULATORY ACTION GUIDANCE:

1. CRITERIA FOR DIRECT ISSUANCE OF A *WARNING* LETTER

Appropriate divisions with the Office of Pharmaceutical Quality Operations (OPQO) are authorized to issue *Warning* Letters in accordance with Chapter 8-10, Regulatory Procedures Manual when the following conditions are met:

a. The firm is engaged in the manufacture, preparation, propagation, compounding or processing of veterinary drugs and is subject to registration *and drug listing* under Section 510 of the Federal Food, Drug, and Cosmetic Act, and is not exempt under any of the provisions of 21 CFR, Part 207

NOTE: Veterinarians compounding prescription drugs for use in their private practice are not required to register. Veterinarians manufacturing drugs for resale must register

b. A current inspection includes an inventory of veterinary drugs on hand.

c. The establishment file documents that top level managers at the facility have been advised verbally or in writing (see REMARKS) of the firm's responsibility to register

d. The appropriate division within OPQO has called the *FDA headquarters unit* responsible for registration *and drug listing* to assure that no registration *or drug listing* forms have been received

2. OTHER LEGAL SANCTIONS

If issuance of the *Warning* Letter does not achieve correction, one of the following legal actions should be recommended to *CVM,* Division of Compliance, HFV-236 within one week after the response period expires:

Seizure

When failure to register *and/or drug list* is the only actionable violation and a firm fails to comply with the *Warning* Letter, seizure of all products whose manufacture necessitates registration and/or in the non-registered firm's possession, is the recommended action. Applicable raw materials may be included to bring a small lot up to seizable size. Do not recommend seizure of lots otherwise believed to be in compliance in the possession of consignees. *An inventory* of the drugs manufactured, repacked, or relabeled should be submitted with the regulatory action request

Injunction

Injunction is only recommended when seizure action cannot be accomplished (short supply items, small lots) or when seizure action fails to bring about correction. Include a full description of the establishment's business activities

Prosecution

For this type of violation - failure to register, *or drug list*, prosecution ordinarily would be inappropriate. The course of action should be designed to result in correction.

REMARKS:

If the firm is found to be a handler of controlled drugs the appropriate Division within OPQO should refer failure to register to:

Drug Enforcement Administration
Department of Justice
1405 Eye Street, N.W.
Washington, D.C. 20537

REFERENCES:

Regulatory Procedures Manual, Chapters 8-10
Section 510, FD&C Act and 21 CFR, Part 207

Example *WARNING* LETTER

President
Deep-Six Drug Co.
101 Wharf Road
Ocean City, Nevada 10625

Dear Mr. Fish:

A review of our files shows that your veterinary drug repackaging establishment located at 101 Wharf Road, Ocean City, Nevada 10625, is not registered *and/or has not drug listed* with the Food and Drug Administration. You have (or Mr. X has) been previously advised of this requirement. This failure constitutes a continued violation of the Federal Food, Drug, and Cosmetic Act.

All drugs manufactured, prepared, propagated, compounded, or processed by your firm are misbranded within the meaning of Section 502(o), because your firm is not registered, and/or has not drug listed as required by Section 510 of the Federal Food, Drug, and Cosmetic Act

As the president of a drug repacking facility, you are responsible for assuring that your overall operation and the products you distribute are in compliance with the law. Failure to do so may result in regulatory action, such as seizure and/or injunction.

The drug registration form and/or drug listing form(s) are enclosed. We request that you complete the form(s) and return them within fifteen (15) days. If these forms cannot be completed within 15 days, state the reason for the delay and the timeframe within which the forms will be completed and returned

Your response should be directed to ____ at the above address.
Sincerely yours,

OPQO Program Division Director
Enclosures

bcc: Additional Responsible Individuals
cc: Distribution as specified in RPM 8-10

Material between asterisks is new or revised
<> Indicates material has been deleted

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