



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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JUL 27 2000

Mr. Thomas O. Henteleff
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street, NW
Washington, DC 20036-6601

RE: 99P-0342

Dear Mr. Henteleff:

This is in further response to your petition dated March 1, 1999, requesting that the Commissioner amend the prescription legend statement, required by 21 Code of Federal Regulations (CFR) §801.109(b)(1), to permit the use of an "Rx only" or "Rx" symbol as a substitute for the prescription legend statement.

In our response to you dated December 23, 1999, we incorrectly referenced docket number 99P-0792 regarding this matter. The docket number we should have referenced is 99P-0342. Our docket management staff was kind enough to advise us of the error and correct the docket files accordingly. We regret any confusion this may have caused you.

Sincerely yours,

Casper E. Uldriks
Special Assistant to the Director
Office of Compliance
Center for Devices and Radiological Health

99P-0342

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