

APPENDIX B

NOTICE OF PROPOSED IMPOSITION OF CIVIL PENALTIES

Pharmatopes, Incorporated
License No. 08-18308-01MD

Docket No. 30-14826
EA-81-03

This Office has considered the enforcement options available to the NRC including administrative actions in the form of written notices of violation, civil monetary penalties, and orders pertaining to the modification, suspension or revocation of a license. Based on these considerations, we propose to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (42 USC 2282) and to 10 CFR 2.205, in the cumulative amount of Seven Thousand Five Hundred Fifty Dollars (\$7,550) for the specific items of non-compliance set forth in Appendix A to the cover letter. In proposing to impose civil penalties pursuant to this section of the Act and in fixing the proposed amount of the penalties, the factors identified in the statements of consideration published in the Federal Register with the rulemaking action which adopted 10 CFR 2.205 (36 FR 16894) August 26, 1971, and the "Criteria for Determining Enforcement Action," which was sent to NRC licensees on December 31, 1974, have been taken into account.

Pharmatopes, Incorporated may, within twenty-five (25) days of the date of this notice pay the civil penalties in the cumulative amount of Seven Thousand Five Hundred Fifty Dollars (\$7,550) or may protest the imposition of the civil penalties in whole or in part by a written answer. Should Pharmatopes, Incorporated fail to answer within the time specified, this office will issue an order imposing the civil penalties in the amount proposed above. Should Pharmatopes, Incorporated elect to file an answer protesting the civil penalties, such an answer may (a) deny the items of noncompliance listed in the Notice of Violation in whole or in part, (b) demonstrate extenuating circumstances, (c) show error in the Notice of Violation, or (d) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate by specific reference (e.g., giving page and paragraph numbers) to avoid repetition.

Pharmatopes, Incorporated's attention is directed to the other provisions of 10 CFR 2.205 regarding, in particular: failure to answer and ensuing orders; answer, consideration by this office, and ensuing orders; requests for hearings, hearings and ensuing orders; compromise; and collection.

Upon failure to pay any civil penalty due which has been subsequently determined in accordance with the applicable provisions of 10 CFR 2.205, the matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Atomic Energy Act of 1954, as amended (42 USC 2282).