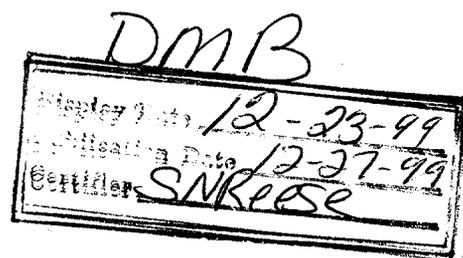


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4461]



**Withdrawal of Guidance Document on Selegiline Hydrochloride Tablets**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing a guidance for industry entitled “Selegiline Hydrochloride Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing.” This guidance, which was issued in December 1995, is being withdrawn because it does not represent current agency thinking on in vivo bioequivalence (BE) and in vitro testing for selegiline hydrochloride.

**DATES:** General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written comments on agency guidance documents to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Aida L. Sanchez, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-857-5847.

**SUPPLEMENTARY INFORMATION:** FDA is withdrawing a guidance for industry entitled “Selegiline Hydrochloride Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing.” This guidance addresses BE and dissolution testing for selegiline. This guidance is being withdrawn because it does not include the appropriate acceptance criteria for parent selegiline in plasma. Based on a new understanding of the pharmacokinetics of selegiline hydrochloride developed since the publication of the selegiline guidance, FDA has been requesting applicants to demonstrate that

the point estimate of the test to reference ratio for area under plasma concentration-time curve (AUC) and peak blood plasma concentration (C<sub>max</sub>) of the parent falls within 80 to 125 percent. These criteria have been used for the demonstration of bioequivalence of all selegiline tablets and capsules currently on the market. In addition, the guidance, which was issued in December 1995, includes information only on selegiline tablets and not selegiline capsules, which have been approved by FDA since the issuance of the guidance to be withdrawn.

The withdrawal of this guidance is part of a long-term effort in the Office of Generic Drugs (OGD) to review guidance documents on the development of generic drug products with the goal of identifying documents that need to be revised, reformatted, or withdrawn because they are no longer current (64 FR 36886, July 8, 1999). OGD hopes the guidance review process will result in guidances for industry that better reflect the current thinking of the agency on generic drug development and that will eliminate the need for drug-specific bioavailability (BA) and BE guidances. A guidance currently under development on BA and BE studies for orally administered drug products will serve as a core guidance on BA and BE once it has been finalized and will replace most product-specific guidances.

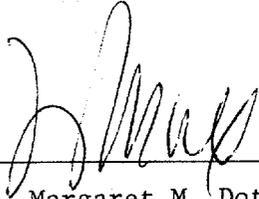
The agency welcomes comments on its efforts to review existing guidances related to the development of drug products and revise, reformat, or withdraw them, as appropriate. This information is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on agency guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with

---

the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9:a.m. and 4 p.m., Monday through Friday.

Dated: 12/15/99  
December 15, 1999



---

Margaret M. Dotzel  
-Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

