## Food and Drug Administration

**[Docket No. 96N–0225]**

## Submission Requirements for All Grant and/or Cooperative Agreement Applications Submitted to the Food and Drug Administration for Funding Consideration

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing changes to its grant and/or cooperative agreement noncompeting continuation application submission requirements for fiscal year (FY) 1997. The Streamlined Noncompeting Award Process (SNAP) was originally implemented by the National Institutes of Health (NIH) in FY 1994, in an effort to simplify the process for submission of information necessary for grantees to receive a noncompeting grant award. By incorporating SNAP into FDA's processes, effective in FY 1997, FDA will be consistent with NIH requirements for the submission and processing of noncompeting continuations.

**FOR FURTHER INFORMATION CONTACT:** Robert L. Robins, Grants Management Officer, Food and Drug Administration (HFA–520), Park Bldg., rm. 3–40, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6170.

**SUPPLEMENTARY INFORMATION:**

I. Eligibility

All grantees covered by the Expanded Authorities are eligible for SNAP. Any grantee excluded from the Expanded Authorities, e.g., those grantees designated as ''Exceptional'' and foreign grantees, would routinely be excluded from SNAP. Additional examples of grantees that would be excluded from SNAP include (but are not limited to) the following: (1) Grantees that require close project monitoring or technical assistance (e.g., first time grantees); (2) grantees that have a consistent pattern of failure to adhere to appropriate reporting deadlines; and (3) any activity that is excluded from SNAP at the discretion of the awarding agency. Applicants applying for FDA's Small Scientific Conference Grant Program or those applying for cooperative agreements are not eligible for SNAP regardless of whether or not they are covered by the Expanded Authorities authorized under other grant programs.

II. Snap Procedures

For a new competitive application received in FY 1997, the applicant must address all years of funding support requested in the Scope of Work or Research Plan, and provide sufficient information needed for evaluation of the entire project, independent of any other documentation. As the funding for the project will be negotiated for all years at the time of the initial competitive segment, the budgets for all years of requested support must be fully justified.

New grantees who receive competitive awards in FY 1997, for which there is a noncompetitive segment, will be required to use the SNAP for future years of support utilizing the instructions listed below in conjunction with the instructions in the PHS 2590 (Rev. 5/95) application kit. Elements in the PHS 2590 that remain the same, e.g., a biographical sketch page for new key personnel and when additional information is required, should use the appropriate pages from the PHS 2590 application.

Instructions:

1. Complete the face page (form page 1), the Progress Report Summary (form page 6), the personnel and study subjects page (form page 7), the checklist page (form page 8), and provide a brief, two page progress report (tables and/or figures that summarize key accomplishments may be in addition to the two pages). It is not necessary to complete the indirect cost portion of the checklist page unless there is a change in the performance site.

2. Answers to the following questions should be inserted before the progress report:

a. Has there been a change in other support of key personnel since the last reporting period? Specific information is to be provided only if active support has changed. If a previously active grant has terminated and/or if a previously pending grant is now active, the change in support is to be reported. Submission of other support information is not necessary if support is pending or for changes in the level of effort for active support reported previously. Other support information should be submitted only for the principal investigator and for those individuals who are considered by the principal investigator to be key to the project. A key person is defined as an individual who contributes in a substantive way to the scientific development or execution of the project, whether or not a salary is requested. Key personnel are defined on page 11 of the PHS 398 grant application kit (Rev. 5/95).

b. Will there be, in the next budget period, significant rebudgeting of funds and/or changes in level of effort for key personnel from what was approved in the current year's budget for this project? Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established at the time of the competing award by more than 25 percent of the total amount awarded, or $250,000, whichever is less. The basis for determining significant rebudgeting excludes the effects of carryover of prior year unobligated balances, but includes competing or administrative supplements. This implementation redefines significant rebudgeting contained in the current PHS Grants Policy Statement (Rev. 4/1/91), pages 8–1 and 8–7.

c. Will there be, in the next budget period, a change in the level of effort for key personnel? A significant change in the level of effort is defined in the Federal regulations (45 CFR 74.25(c)(3)) as a 25 percent reduction in time/effort devoted to the project. For example, if a key person on the project is expected to reduce his/her effort from 40 percent to 30 percent, which represents a 25 percent reduction in the level of effort, the detailed budget page (form page 2) and the budget justification page (form page 3) are to be submitted in the noncompeting continuation. This requirement applies regardless of whether or not the key person is compensated from the grant.

3. Explain any estimated unobligated balance (including prior year carryover) that is greater than 25 percent of the current year's total budget or more than $250,000. An estimated unobligated balance that meets this criterion is to be reported on the Progress Report Summary page (form page 5). An explanation of why there is a significant balance and how it will be spent if carried forward into the next budget period is to be provided.

The questions regarding other support and significant rebudgeting and/or change in level of effort must be answered by stating that no change has occurred or is planned. If a change has occurred or is planned, the appropriate form and/or justification is to be submitted in the noncompeting continuation application. Information regarding unobligated balances must be provided when it is anticipated that there will be an unobligated balance (including prior year carryover) of 25 percent of the current year's total budget, or more than $250,000.

The Progress Report Summary (form page 5) is to be used to provide the requested information, which should be provided before beginning the progress report. The progress report instructions

contained on pages 7 through 9 of the PHS 2590 (Rev. 5/95) form should be followed for reporting on research progress. Supplemental reporting instructions may be required depending on different FDA grant program requirements. After reviewing the noncompeting continuation application, the FDA program and/or grants management staff may require additional information to evaluate the project for continued funding. Failure to provide this information in a timely manner may result in a delayed award.

FDA grants are funded under the legislative authority of section 301 of the Public Health Service Act (24 U.S.C. 241).

Dated: August 9, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

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**[Docket Nos. 96P–0190/CP1, 96P–0197/CP1, 96P–0251/CP1]**

## Determination That Selegiline Hydrochloride 5-Milligram Tablet Was Not Withdrawn From Sale For Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that selegiline hydrochloride (Eldepryl®) 5-milligram (mg) tablet was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for selegiline hydrochloride 5-mg tablet.

**FOR FURTHER INFORMATION CONTACT:** Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Selegiline hydrochloride (Eldepryl®) 5-mg tablet is the subject of approved NDA 19–334, held by Somerset Pharmaceuticals, Inc. (Somerset). On May 17, 1996, Somerset withdrew the selegiline hydrochloride 5-mg tablet from sale, and began marketing in its place a capsule form of selegiline hydrochloride 5-mg (NDA 20–647).

On June 12, 1996, Novopharm Ltd. submitted under 21 CFR 10.30 a citizen petition (Docket No. 96P–0190/CP1) regarding the status of the selegiline hydrochloride 5-mg tablet. Two similar citizen petitions were subsequently received by the agency; a petition by Endo Laboratories, L.L.C. was filed on June 17, 1996 (Docket No. 96P–0197/CP1), and a petition submitted by Williams & Connolly on behalf of Alphapharm, Ltd. was filed on July 10, 1996 (Docket No. 96P–0251/CP1). The three petitions request that the agency determine whether the selegiline hydrochloride 5-mg tablet was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, keep the drug listed in the Orange Book.

The agency has reviewed its records and under § 314.161, has determined that the selegiline hydrochloride 5-mg tablet was not withdrawn from sale for reasons of safety or effectiveness. In reaching its decision, FDA considered comments submitted by Somerset, in which Somerset asserted that the drug was withdrawn from sale for safety reasons. Somerset requested that FDA deny the citizen petitions.

Somerset claims that Eldepryl® 5-mg tablet was withdrawn from the market ''out of concern for the safety of patients with Parkinson's Disease.'' First, it refers to the appearance of counterfeit Eldepryl® tablets in the U.S. marketplace. This is not a problem unique to Eldepryl® and is not evidence that the product is unsafe.

Second, Somerset makes a nonspecific reference to ''the information contained in NDA # 19–334'' as confirmation that the removal of the tablet form of the drug was out of concern for the safety of patients. FDA's examination of this NDA found no evidence to support this claim. Somerset may have been alluding to reports of difficulty swallowing tablets in patients with Parkinson's Disease. That some patients may prefer an alternative dosage form is common with oral products regardless of the disease being treated. FDA does not regard providing a second dosage form that some patients may find more convenient than the first as evidence that the first is unsafe. Somerset may also have been alluding to reports of confusion between Eldepryl® tablets and enalapril. This is not a safety concern relevant to generic products because, among other reasons, they would not use the name Eldepryl® .

The agency concludes that Eldepryl® tablets were withdrawn from sale for reasons other than for safety or effectiveness. Accordingly, the agency will maintain selegiline hydrochloride 5-mg tablet in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to selegiline hydrochloride 5-mg tablet may be approved by the agency.

Dated: August 9, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

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