

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

JMB

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**Food and Drug Administration**

**Studies of Adverse Effects of Marketed Drugs; Availability of Grants (Cooperative Agreements); Request for Applications; Correction**

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

**ACTION:** Notice; correction.

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**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 4, 2001 (66 FR 17907). The document announced the anticipated availability of funds for cooperative agreements to study adverse affects of drugs marketed in the United States and its territories. The document was published with some inadvertent errors. This document corrects those errors.

**DATES:** Submit applications by June 4, 2001.

**ADDRESSES:** Application kits are available from, and completed applications should be submitted to Rosemary T. Springer, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7182.

**Note:** Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20852. Please DO NOT send applications to the Center for Scientific Review (CSR), National Institutes of Health. Applications mailed to CSR and not received by FDA in time for orderly processing will be returned to the applicant without consideration. Application forms can also be found at <http://www.nih.gov/grants/phs398/forms-toc.html>.

**FOR FURTHER INFORMATION CONTACT:** Rosemary T. Springer, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7182.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 01-8246, appearing on page 17907 in the **Federal Register** of Wednesday, April 4, 2001, the following corrections are made:

1. On page 17910, in the first column, section VI.B.1.b is corrected to read as follows:

*b. Size (70 points).* Applicants should list number of patients enrolled in their database as of December 31, 2000.

- >3 million covered lives (70 points)
- >2.5 to 3 million covered lives (40 points)
- >2 to 2.5 million covered lives (30 points)
- >1.5 to 2 million covered lives (10 points)

2. On page 17910, in the first column, section VI.B.1.c is corrected to read as follows:

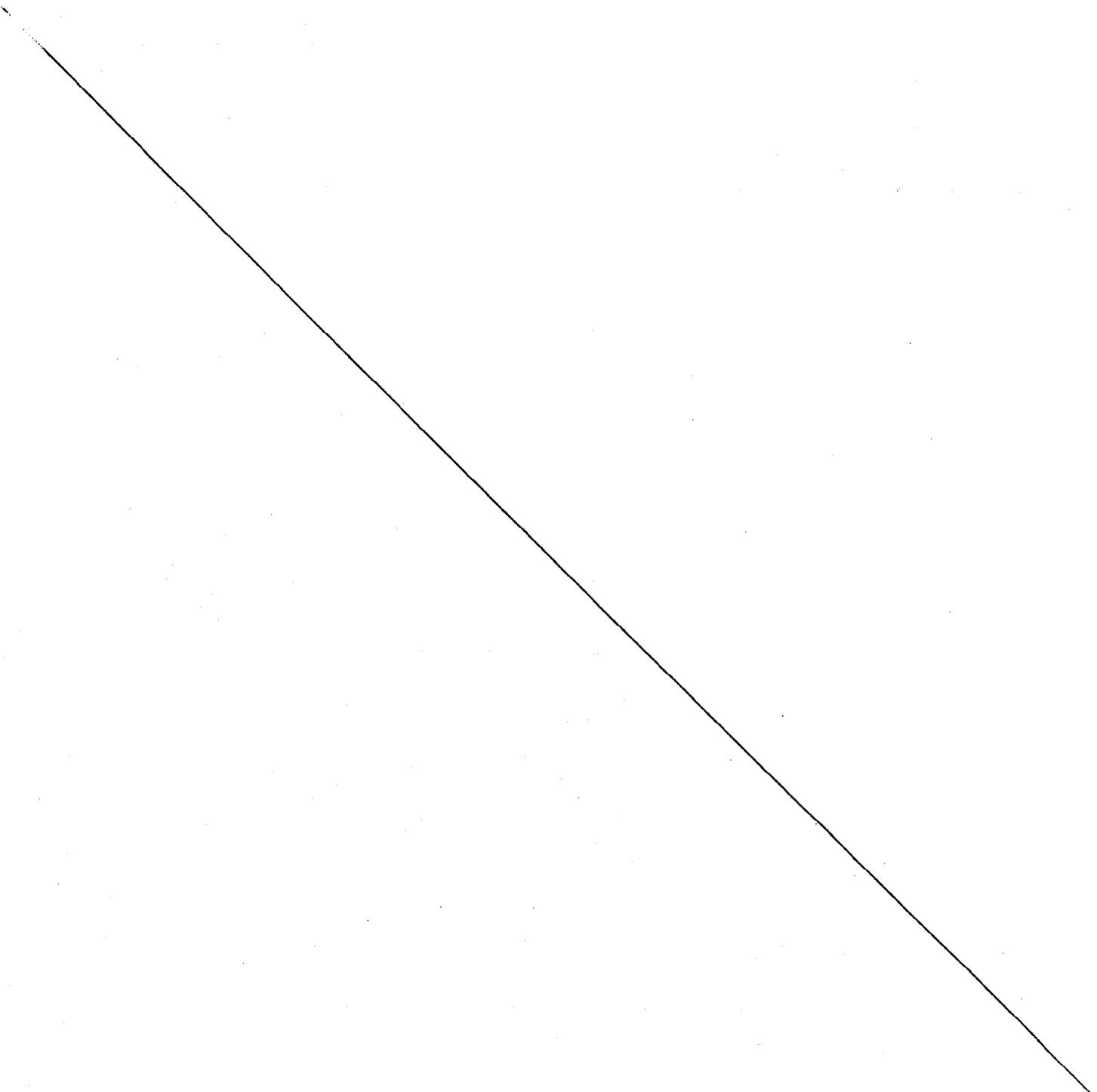
*c. Duration (55 points).* The calendar time-period for which detailed patient longitudinal data are available and linked for routine, day-to-day analysis from at least 80 percent of the multiple State sites.

- <5 years of data online (0 points)
- 5 years of data online (25 points)
- 6 points for each additional year beyond 5 years of online data to a possible total of 55 points

3. On page 17910, in the third column, section VI.B.2. is corrected to read as follows:

2. New Molecular Entity (NME) Identification (200 points)

In table 1 of this document, 40 recently approved NMEs are listed. Applicants should respond with the number of unique patients in their system with at least 1 outpatient prescription for each of the 40 drug products listed in table 1. For each drug, points will be awarded by the review panel according to the following schedule:

- >25,000 exposed patients (5 points)
  - 20,001 to 25,000 exposed patients (4 points)
  - 15,001 to 20,000 exposed patients (3 points)
  - 10,001 to 15,000 exposed patients (2 points)
  - 5,001 to 10,000 exposed patients (1 point)
  - 5,000 or fewer exposed patients (0 points).
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Dated: 4-17-01  
April 17, 2001.

William Hubbard

William K. Hubbard,  
Senior Associate Commissioner for  
Policy, Planning, and Legislation.

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

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Suzette N. Reese