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Certifier D. Hawkins

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Establishment of Medical Device User Fee Rates for Fiscal Year 2003 and  
Interim Procedures; 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 November 21, 2002 (67 FR 70228). The document announced the rates and interim procedures for medical device user fees for fiscal year (FY) 2003. The document was inadvertently published with confusing language regarding the fee that must be paid by a small business that submits a 510(k) premarket notification for FDA review during FY 2003. The document intended to state that all 510(k)s submitted for FDA review during FY 2003 are subject to a standard fee of \$2,187, and that all submitters who are subject to a fee, including a small business, are required to pay this fee. This document corrects that error.

**ADDRESSES:** Persons with access to the Internet may obtain further information on the Medical Device User Fee and Modernization Act of 2002 at <http://www.fda.gov/cdrh/mdufma> or <http://www.fda.gov/cber/mdufma/mdufma.htm>.

**FOR FURTHER INFORMATION CONTACT:** Frank Claunts, Office of Management and Systems (HFA-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4427.

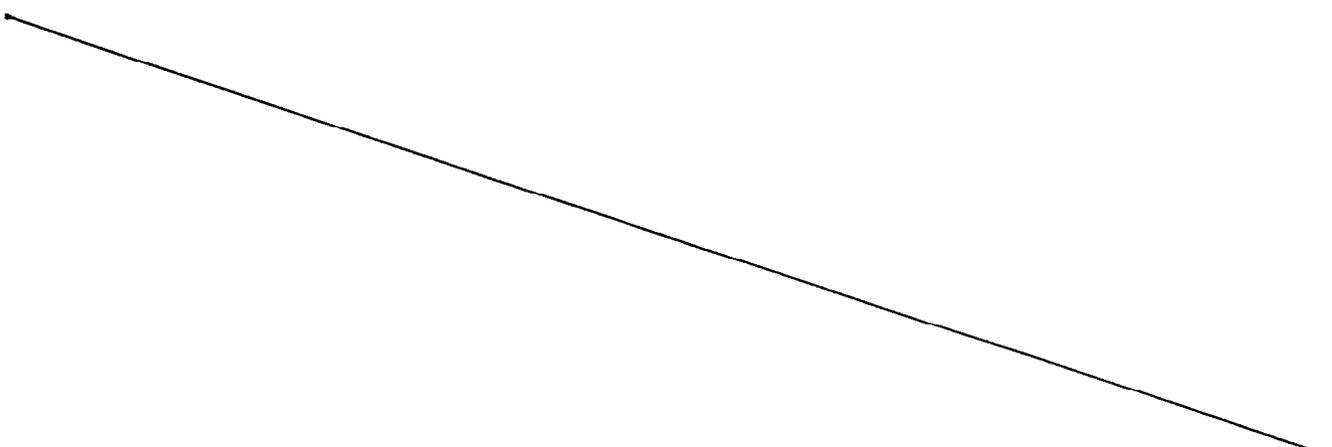
**SUPPLEMENTARY INFORMATION:** In FR Doc. 02–29572, appearing on page 70228 in the **Federal Register** of Thursday, November 21, 2002, the following corrections are made:

1. On page 70228, in the third column, under “III. Fee Calculations for FY 2003,” the fourth sentence is corrected to read “Table 1 of this document summarizes the types of applications that are subject to a fee, the full fee amount expressed as a percent of the fee for a PMA, the full (standard) fee for FY 2003, and the fee that may be paid by a qualified small business.”

2. On page 70229, in the second column, the first full sentence is corrected to read “For premarket notification submissions, a small business will pay the full (standard) fee of \$2,187.”

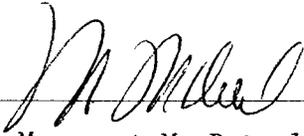
3. On page 70229, in table 1, in the third column, in the last row, “2,187” is corrected to read “2,187<sup>1</sup>”.

4. On page 70229, under table 1, add the following footnote to read as follows: “<sup>1</sup>A small business will pay the full (standard) fee of \$2,187 for a premarket notification submitted to FDA during FY 2003. A small business fee, set at 80 percent of the standard 510(k) fee, will be available beginning FY 2004.”



Dated: 1/6/03

January 6, 2003



Margaret M. Dotzel,  
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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