DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

Neurological Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is correcting a neurological device classification regulation. FDA is changing the name of the device from ''cottonoid paddie'' to ''neurosurgical paddie.'' FDA is making this change because interested persons have advised FDA that the word ''cottonoid'' is a registered trademark and its use has created problems for competitors of the company that has registered the trademark. FDA is also removing the word ''cotton'' from the identification because devices of this type are not always made of cotton.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 4, 1979 (44 FR 51758), FDA published a final rule to classify the cottonoid paddie, a neurological device into class II (performance standards at that time). Only recently, several people have brought to the attention of FDA that the word, cottonoid, is a registered

trademark, of Johnson & Johnson. These persons pointed out that the use of this classification name has created some problems for competitors of Johnson & Johnson. FDA is therefore changing the name of the device from cottonoid paddie to neurosurgical paddie. FDA is also removing the word ‘‘cotton’’ from the identification of the device because many of the devices of this type are made of materials other than cotton.

II. Environmental Impact

The agency has previously determined under 21 CFR 25.30(i) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required. The changes in these amendments do not alter this conclusion.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule only changes the name of the device and does not change

in any way how the device is regulated, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Paperwork Reduction Act of 1995

FDA has determined that this final rule contains no additional collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 882

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 882.4700 is amended by revising the section heading and paragraph (a) to read as follows:

§ 882.4700 Neurosurgical paddie.

(a) A neurosurgical paddie is a pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

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Dated: February 25, 2004.

Beverly Chernaik Rothstein,

Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.

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