

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. 2004N-0461]

DDM

Display Date	11-14-05
Publication Date	11-15-05
Officer	A. Corbin

Environmental Assessment; Categorical Exclusions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation on environmental impact considerations to expand existing categorical exclusions to include approvals of humanitarian device exemptions (HDEs) and establishment of special controls as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. FDA is taking this action in accordance with the National Environmental Policy Act (NEPA).

DATES: This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2346.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of November 24, 2004 (69 FR 68280), FDA published a proposed rule (the November 2004 proposed rule) to amend its

regulation on environmental impact considerations to expand existing categorical exclusions to include approvals of HDEs and establishment of special controls as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an EIS is required. Interested persons were given until December 27, 2004, to comment on the proposal. FDA received two comments on the proposed rule.

II. Summary of Comments and FDA's Response

(Comment 1) One comment opposed FDA's proposal to expand existing categorical exclusions to include approvals of HDEs and establishment of special controls on the basis that a more rigorous standard should be applied before approval of "dangerous devices."

(Response) This comment seemed to misunderstand the proposed rule. FDA is not excluding any products from the statutorily required safety review under the Federal Food, Drug, and Cosmetic Act. The rule excludes certain categories of actions from the need to prepare an EA or EIS under the NEPA.

(Comment 2) This comment did not express an opinion on the proposed rule.

III. Background and Regulatory Authorities

NEPA requires all Federal agencies to assess the environmental impacts of its actions and to ensure that the interested and affected public is informed of environmental analyses. The Counsel on Environmental Quality (CEQ) is responsible for overseeing Federal efforts to comply with NEPA. Both CEQ and FDA have issued regulations governing agency obligations and responsibilities under NEPA. CEQ's regulations implementing the procedural requirements of NEPA can be found at 40 CFR parts 1500 through 1508 and FDA's NEPA policies and procedures can be found at 21 CFR part 25.

CEQ's and FDA's regulations, 40 CFR 1508.4 and 21 CFR 25.5(a)(1), respectively, define "categorical exclusion" to mean a category of actions which have been found by procedures adopted by the Federal agency not to individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EA nor an EIS is required. When categorically excluding an action, an agency must determine that there are no extraordinary circumstances related to the action that may result in the action having significant environmental effects.

FDA published final regulations governing compliance with NEPA as implemented by the CEQ regulations in the **Federal Register** of July 29, 1997 (62 FR 40570). The July 29, 1997, final rule listed certain device actions as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an EIS is required.

IV. Summary of the Final Rule

FDA received two comments on the proposed rule, however, neither comment related to the statutory and regulatory authority of that proposal. Therefore, the discussion of the statutory and regulatory authority set out in the preamble of the proposed rule (69 FR 68280 at 68281 through 68282) remains relevant to this final rule and will not be repeated here.

A. Special Controls

FDA is amending its environmental impact regulations under § 25.34 to include as a category of action that does not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor EIS is required, classification or reclassification of a device, including the establishment of special controls, if the action will not result in increases in

the existing levels of use of the device or changes in the intended use of the device or its substitutes. FDA issues special controls in order to assure that class II devices provide a reasonable assurance of safety and effectiveness. Under these conditions, FDA believes that it is appropriate to categorically exclude the establishment of a special control from the requirement to prepare an EA or EIS.

B. HDE

FDA is amending § 25.34 to include approval of an HDE as a category of action that does not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor EIS is required. Because humanitarian use devices are limited by definition to use for treating or diagnosing diseases or conditions affecting fewer than 4,000 individuals in the United States per year, any environmental impact associated with use of a humanitarian use device is very limited. FDA approves few HDEs, further limiting any potential environmental impact. FDA's experience in reviewing HDEs has shown that no HDE reviewed thus far has had a significant environmental impact.

V. Environmental Impact

The agency has determined that under 21 CFR 24.30(h) this action 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 is required.

VI. 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 not a significant regulatory action 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 final rule provides for an exclusion from the requirement to prepare an EA or EIS and, as such, relieves a burden, the agency certifies that this final rule will not have a significant economic impact on substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before finalizing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. 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.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of the Food and Drug Administration, 21 CFR part 25 is amended as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

■ 1. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

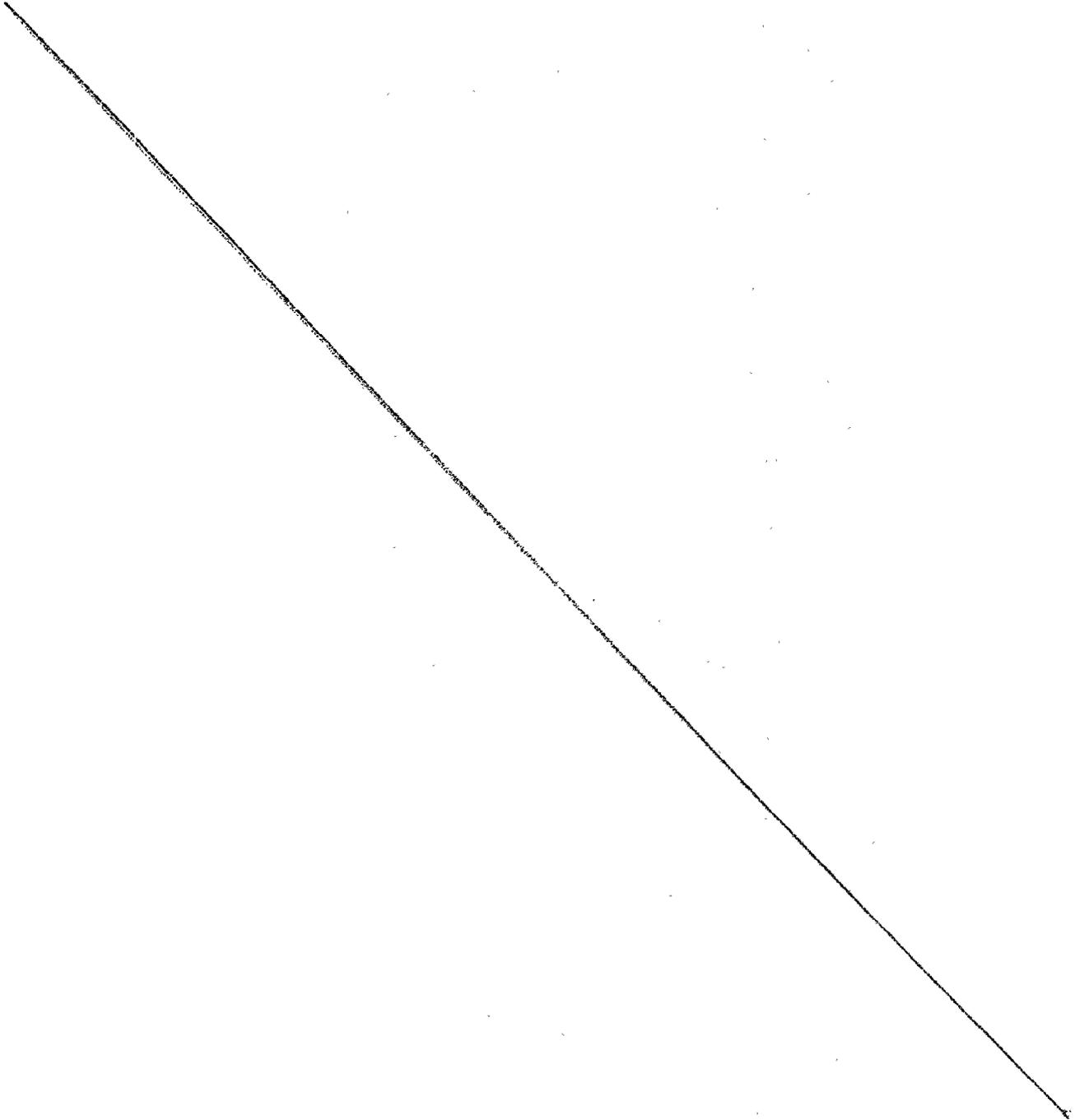
■ 2. Section 25.34 is amended by revising paragraph (b) and adding paragraph (i) to read as follows:

§ 25.34 Devices and electronic products.

* * * * *

(b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.

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(i) Approval of humanitarian device exemption under subpart H of part 814 of this chapter.

Dated: 10/14/05
October 14, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

