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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864, 866, 868, 870, 872, 874, 876, 878, 884, 886, and 888

[Docket No. 99N-0035]

Medical Devices; Reclassification of 38 Preamendments Class III Devices into Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 90 days the comment period for the submission of comments regarding 3 of the 38 devices proposed for reclassification from class III into class II. The proposed rule was published in the **Federal Register** of March 15, 1999 (64 FR 12774). The agency is taking this action in order to allow more time to submit comments to FDA regarding the guidance documents that were not made available when the March 15, 1999, proposed rule was published. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability for comment of two guidance documents that are special controls for three devices.

DATES: Submit written comments on the proposed rule by *[insert date 90 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices. Interested persons were given until June 14, 1999, to comment on the proposed rule.

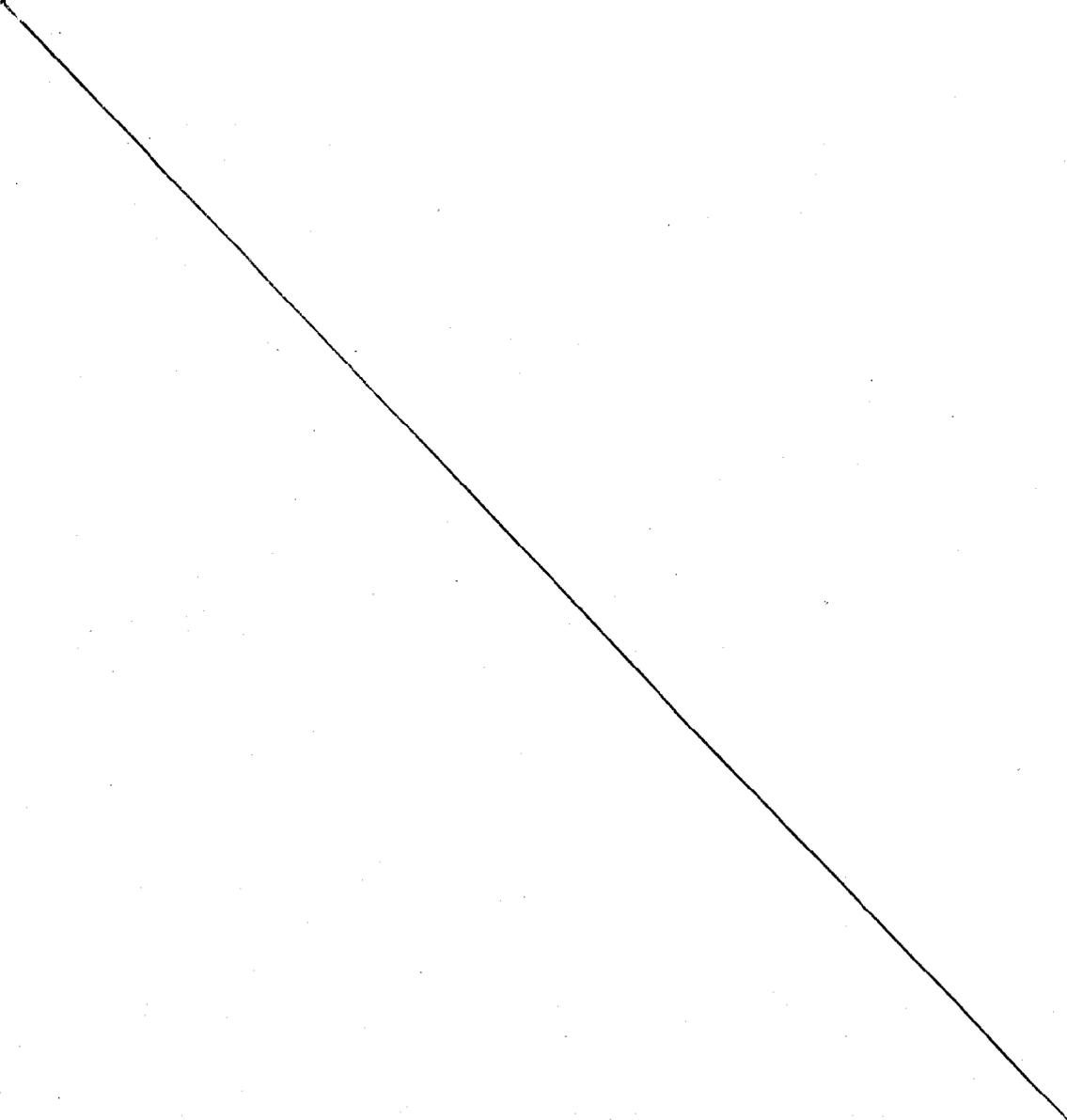
A trade association requested that FDA reopen the comment period for 6 of the 38 devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through the agency's good guidance practices (GGP's). The request further noted that it was impossible to comment on the proposed reclassification without the guidance documents being available. Therefore, the trade association requested that FDA extend the comment period until at least 90 days after the guidance documents became publicly available for comment. In the **Federal Register** of April 19, 2000 (65 FR 20933), FDA reopened the comment period on the proposed reclassification of those six devices.

FDA also identified an additional three devices for which the agency had not issued the guidance documents proposed as special controls for comment in accordance with the GGP policy. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability for comment of two guidance documents that are special controls for three devices. Accordingly, FDA is reopening the comment period for the March 15, 1999, proposed rule to allow additional time for interested persons to comment on the following three devices:

- Indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer (21 CFR 868.1150),
- Indwelling blood hydrogen ion concentration (pH) analyzer (21 CFR 868.1170), and
- Indwelling blood oxygen partial pressure (P_{O_2}) analyzer (21 CFR 868.1200).

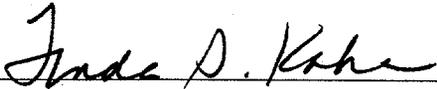
II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the proposed rule only with respect to the three devices listed above by [*insert date 90 days after date of publication in the Federal Register*]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified



with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/31/00
October 31, 2000.



Linda S. Kahan,
Deputy Director for Regulations Policy Center for Devices and Radiological Health.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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