and (f)(1)). FDA took this position following the Obstetrics and Gynecology Devices Panel meeting, after considering the Obstetrics and Gynecology Devices Panel's recommendation, after further evaluation of the available scientific literature, and following further consultation with outside medical experts. FDA concluded that the transillumination devices are not clinically effective for the diagnosis or detection of breast cancer or other breast abnormalities or conditions, and that the use of the technique may contribute to the delay of detection of lesions in the early stages of cancer, when the disease is most treatable.

At this time, therefore, the distribution of breast transillumination devices or any multipurpose transillumination device that is labeled, promoted, or intended for use in the breast is in violation of the law, regardless of whether the device is labeled for independent use or adjunctive use with mammography. FDA has initiated enforcement actions against manufacturers who have continued to distribute transilluminators.

When these devices become subject to the premarket approval process, the manufacturer of each individual device will have an opportunity to demonstrate the safety and effectiveness of the device for its indicated use. Any further decision on adjunctive use versus stand alone use will be based on valid scientific data presented by manufacturers in the PMA's they submit at that time.

FDA intends to publish pursuant to section 515(b) of the act, a proposed rule to establish the effective date of the requirement for premarket approval for transilluminators. Such a rule will be published after the effective date of a final classification regulation based on this proposed rule. A PMA may be required 30 months after the effective date of the final rule classifying the device in class III under section 513 of the act or 90 days after publication of the final rule requiring premarket approval under section 515(b), whichever is later. After the establishment of an effective date for the requirement of PMA submissions for these devices, any transilluminators for use on breast tissue that are being marketed without a PMA will be considered adulterated under section 501(f)(2) of the act (21 U.S.C. 351(f)(2). However, as noted earlier, FDA has determined, in light of scientific data that has become available, that transilluminators for use in the breast are already misbranded under sections 502(a) and 502(f)(1) of the act and should not be marketed at this time.

FDA concludes that because the transilluminator is a diagnostic imaging device, it would be more appropriately classified as a radiological device. The agency therefore proposes to classify it in part 892 (21 CFR part 892) of the regulations (radiology devices) instead of part 884 (21 CFR part 884) of the regulations (obstetrical and gynecological devices).

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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V. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that 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 proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory