through 0573 inclusive: Before or in conjunction with the actions specified in paragraph (d)(2) of this AD, modify the high stage pilot valve located in the aft accessory compartment (including purging the sense lines and revising wiring of the high stage pilot valve), in accordance with McDonnell Douglas Service Bulletin MD11–36–018 R01, Revision 1, dated July 18, 1995.

Note 5: In addition to the procedures for modification of the high stage pilot valve located in the aft accessory compartment, McDonnell Douglas Service Bulletin MD11–36–018 R01, Revision 1, dated July 18, 1995, also describes procedures for modification of the high stage pilot valve of the left and right wings. Accomplishment of modification of the high stage pilot valve of the left and right wings is NOT necessary to comply with the optional action provided by paragraph (d)(1) of this AD.

Note 6: Modification of the high stage pilot valve of the aft accessory compartment accomplished before the effective date of this AD in accordance with McDonnell Douglas Service Bulletin MD11–36–018, dated March 28, 1995, is considered acceptable for compliance with the actions specified in paragraph (d)(1) of this AD.

(2) For airplanes having manufacturer's fuselage numbers 0447 through 0552 inclusive, and 0554 through 0608 inclusive: Disconnect and splice together the heater tape wires of the pneumatic sense lines for the high stage and fan air valves from the terminals strips in the lower vertical stabilizer, in accordance with McDonnell Douglas Service Bulletin MD11–36–026, dated September 30, 1996.

(3) For airplanes having manufacturer's fuselage numbers 0447 through 0552 inclusive, and 0554 through 0608 inclusive: Before or in conjunction with the actions specified in paragraph (d)(4) of this AD, modify and reidentify the pilot pressure regulator valve located in the aft accessory compartment (including purging the sense lines and revising the wiring of the pilot pressure regulator valve), in accordance with McDonnell Douglas Service Bulletin MD11–36–025 R01, Revision 01, dated July 31, 1997.

Note 7: In addition to the procedures for modification and reidentification of the pilot pressure regulator valve located in the aft accessory compartment, McDonnell Douglas Service Bulletin MD11–36–025 R01, Revision 01, dated July 31, 1997, also describes procedures for modification and reidentification of the pilot pressure regulator valve of the left and right wings. Accomplishment of the modification and reidentification of the pilot pressure regulator valve of the left and right wings is *not* necessary to comply with the optional action provided by paragraph (d)(3) of this AD.

Note 8: Modification and reidentification of the pilot pressure regulator valve of the aft accessory compartment accomplished before the effective date of this AD in accordance with McDonnell Douglas Service Bulletin MD11–36–025, dated February 14, 1997; is considered acceptable for compliance with the actions specified in paragraph (d)(3) of this AD.

(4) For airplanes having manufacturer's fuselage numbers 0447 through 0464 inclusive, 0466 through 0552 inclusive, and 0554 through 0620 inclusive: Disconnect the heater tape wires from their respective terminal strips and splice the wire ends together, in accordance with McDonnell Douglas Service Bulletin MD11–36–028, dated December 7, 1998.

Reporting

(e) Within 10 days after accomplishing any inspection required by paragraph (b) of this AD, submit a report of the inspection results (only negative findings) to the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate, 3960 Paramount Boulevard, Lakewood, California 90712–4137; fax (562) 627–5210. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

Alternative Methods of Compliance

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 9: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Special Flight Permits

(g) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on July 7, 2000.

John J. Hickey,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–17758 Filed 7–12–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 58, 170, 171, 174, and 179

[Docket No. 99N–5556]

Food Additives: Food Contact Substance Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement the premarket notification process for food contact substances (FCS's) established by the Food and Drug Administration Modernization Act (FDAMA) of 1997. Once implemented, the notification process will be the primary method for authorizing new uses of food additives that are FCS's. FDA is proposing regulations that identify the circumstances under which a food additive petition (FAP) will be required to authorize the use of an FCS; specify the information required in a notification for an FCS; describe the administration of the notification process; and establish the procedure by which the agency may deem a notification to no longer be effective. Additionally, FDA is announcing elsewhere in this issue of the **Federal Register** the availability of an administrative guidance document relating to the preparation of premarket notifications (PMN's).

DATES: Submit written comments by September 26, 2000, except that comments regarding information collection provisions should be submitted by August 14, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION:

I. Background

A. History

In 1958, Congress amended the Federal Food, Drug, and Cosmetic Act (the act) to require premarket approval of food additives (sections 201(s), 402(a)(2)(C), and 409 (21 U.S.C. 321(s), 342(a)(2)(C), and 348)). ''Food additive'' is defined in section 201(s) of the act as ''any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food * * *,'' unless such substance is generally recognized as safe (GRAS) by qualified experts or is prior sanctioned for its intended use. Under section 409 of the act as originally established, food additives require premarket approval by FDA and publication of a regulation authorizing their intended use. Subsequently, in 1995, FDA codified a process, the ''threshold of regulation'' process (§ 170.39 (21 CFR 170.39)), by which certain food additives may be exempted from the requirement of a listing regulation if the substance is expected to migrate to food at only negligible levels (60 FR 3658, July 17, 1995).

More recently, FDAMA (Public Law 105–115) amended section 409 of the act to establish a PMN process as the primary method for authorizing new uses of food additives that are FCS's. A ''Food Contact Substance'' is defined in section 409(h)(6) of the act as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' FDA expects most new uses of FCS's that previously would have been regulated by issuance of a listing regulation in response to a FAP or would have been exempted from the requirement of a regulation under the threshold of regulation process will be the subject of PMN's. Historically, FDA has used the term ''food contact material'' to refer to the ''materials'' mentioned in the definition of an FCS; a food contact material may consist of one or more food contact substances. For the purposes of this document a food contact material is any material intended for use in contact with food (e.g., packaging and food processing equipment).

While developing this proposed rule, FDA convened a public meeting on March 12, 1999 (hereinafter referred to as the March 1999 public meeting), to provide interested parties with an opportunity to comment on FDA's current thinking on administration of the PMN process, and on the agency's recommendations on chemistry and toxicology data for PMN's. FDA has considered those comments in developing this proposal. FDA has filed copies of the transcript of the meeting and the comments received from interested parties with the Dockets Management Branch (address above) (Docket No. 99N–0235). The transcript and comments are available for public review at the Dockets Management Branch.

B. Scope of the PMN Process

The FDAMA amendments and their legislative history make clear that the PMN process is to be the preferred process for authorizing new uses of FCS's. Specifically, section 409(h)(3)(A) of the act states that the PMN process shall be utilized for authorizing the marketing of FCS's except where the Secretary of Health and Human Services determines that the submission and review of a petition is necessary to provide adequate assurance of safety, or where FDA and any manufacturer or supplier agree that a petition may be submitted. (See S. Rept. 105–43, 105th Cong., 1st sess. 46 (1997); H. Rept. 105–306, 105th Cong., 1st sess. 19 (1997).) Section 409(h)(3)(B) of the act authorizes FDA to issue regulations to identify those circumstances under which a petition shall be required, considering criteria such as probable exposure to and potential toxicity of the FCS (21 U.S.C. 348(h)(3)(B)). Below, FDA is proposing regulations identifying the circumstances in which a FAP would be required to authorize the use of an FCS.

C. Comparison to the Food Additive Petition Process

Under the FAP process, a petitioner is required to show that the intended use of the food additive, including an FCS, is safe within the meaning of section 409(c)(3)(A) of the act. FAP's must contain information that addresses the identity of the food additive, the manufacture and the intended conditions of use of the food additive, and the safety of the food additive under its intended conditions of use. Within 15 days of receipt of the petition, FDA determines whether the information in the petition is adequate for filing and notifies the petitioner in writing. If the petition is filed, FDA publishes a notice in the **Federal Register** announcing the filing of the petition. Data and information submitted in a FAP are available for public disclosure once a filing notice for the petition has published. Once a petition is filed, FDA has up to 180 days to respond to the petition. If the petitioner delivers additional substantive information to the agency, either in response to agency questions or on the petitioner's own initiative, the petition is given a new filing date and the statutory clock begins to run anew. Once the agency concludes its review, the agency publishes an order in the **Federal Register**. Such order either includes a regulation that lists the conditions of use for the food additive FDA has determined to be safe or denies the petition and gives the reasons for the agency's decision. Importantly, regardless of the time that passes after the notice of filing publishes, a food additive may not be legally marketed for the petitioned use until FDA publishes an authorizing regulation.

New section 409(h) of the act establishes a different process for food additives that are also FCS's. Under the PMN process for FCS's, a manufacturer or supplier of an FCS must notify FDA at least 120 days before marketing the FCS. The notification must include information on the identity and intended use of the FCS and describe the basis for the notifier's determination that the intended use is safe within the meaning of section 409(c)(3)(A) of the act. As with the FAP process, the burden is on the notifier to demonstrate the safety of the intended use of the FCS. If the information in the notification does not support the notifier's determination of safety, FDA has 120 days from the date of receipt of the notification to object and thereby, to prevent marketing of the substance. If the agency does not object to the notification within the 120 days, the substance may be legally marketed for the notified use. Section 409(h)(4) of the act requires FDA to keep confidential any information submitted in a premarket notification for the 120-day review period. Once the 120-day review period ends, information in the notification is disclosable except for trade secret and confidential commercial information.

The FAP process and the PMN process have two important similarities. First, under both processes, the petitioner or notifier bears the burden of demonstrating that the intended use of the FCS is safe. Second, for both processes, the applicable safety standard

is the standard in section 409(c)(3)(A) of the act.

There are also two important differences between the FAP process and the PMN process. First, in contrast to the petition process, in the PMN process, FDA is not required to publish an order announcing the agency's decision and, if appropriate, an authorizing regulation, in response to a notification. Second, under the petition process, once FDA publishes an authorizing regulation for a specific use of a food additive, any person may legally manufacture and market the food additive for the approved use. In contrast, under section 409(h)(6) of the act, a notification for an FCS is not effective for a similar or identical substance manufactured or prepared by anyone other than the manufacturer identified in the notification. Thus, additional manufacturers who wish to market the same FCS for the same use must also submit a notification to FDA.

II. Proposed Regulations for the Notification Process for Food Contact Substances

This section discusses the regulations that FDA is proposing to implement the notification process for FCS's. Additionally, FDA is announcing elsewhere in this issue of the **Federal Register** the availability of an administrative guidance document relating to the preparation of PMN's. FDA has previously announced the availability of two draft guidance documents on FDA's recommendations for chemistry and toxicology information to be included in PMN's in a notice published in the **Federal Register** of November 12, 1999 (64 FR 61648). Finally, in a direct final rule and companion proposed rule published in the **Federal Register** of May 11, 2000 (65 FR 30352 and 65 FR 30366, respectively), FDA announced that it was amending its regulations on environmental impact considerations to permit notifiers to claim in PMN's the categorical exclusions currently applicable to FAP's and threshold of regulation exemption requests for FCS's.

A. The Definition of a Food Contact Substance

The premarket notification process described in section 409(h) of the act applies only to food additives that are FCS's. As noted in section I.A of this document, an FCS is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in food. FDA is proposing to codify the statutory definition of an FCS in proposed § 170.3(e)(3). In addition, FDA is proposing to amend the definition in § 170.3(e)(2) *Uses of food additives not requiring a listing regulation* (21 CFR 170.3(e)(2)) to include FCS's that are the subject of effective notifications. Notifications are required only for FCS's that are food additives; FCS's that are prior sanctioned or GRAS for their intended use do not require premarket notification to FDA.

In the past, FDA has informally characterized a food additive as being a ''direct additive'' if it was intended to have a technical effect in food, a ''secondary direct additive'' if it was intended to have a technical effect on food during food processing but not in the finished food as consumed, or an ''indirect additive'' if it was intended to have a technical effect in a food contact material. Even though each of these types of food additives is regulated in separate sections of Title 21 of the Code of Federal Regulations, no definition for direct, secondary direct, or indirect food additives exists in the codified regulations or the statute. PMN's will be accepted for unapproved uses of food additives that meet the definition of an FCS regardless of the location in the Code of Federal Regulations of any related codified approval.

In response to the March 1999 public meeting, FDA received comments from interested persons requesting that the agency accept notifications for two types of mixtures of FCS's. The first type of mixture of FCS's is a food contact substance ''formulation'' where all the FCS's in the mixture already may be legally marketed for their intended use in contact with food. FDA's current view on notifications for these mixtures, which will be referred to as ''formulations,'' is discussed in section III of this document.

The second type of mixture of FCS's is a finished food contact material containing one or more FCS's that may not be legally marketed for their intended use at the time FDA receives the notification for the mixture, because the substances are unapproved food additives. FDA has tentatively concluded that a notification for a food contact material containing a new FCS may be submitted under section 409(h) of the act. FDA currently believes that a notification for a mixture of FCS's containing one or more new FCS's would be comparable to a FAP for the use of an indirect food additive in combination with a particular polymer or other food contact material. In this case, the types of polymers with which a petitioned substance is regulated for use represent a limitation on the conditions of use for which the petitioned substance is authorized. Therefore, FDA currently believes that the conditions of use for an FCS that is the subject of a PMN could include detailed specifications on the other FCS's that may be used in combination with the notified FCS. However, FDA is concerned that it could be burdensome for FDA to review within the review period for a PMN a notification for more than one new FCS in a food contact material. Therefore, FDA has tentatively decided that a separate notification must be submitted for each new FCS intended for use in a given food contact material. In other words, a food contact material that includes a new use for two or more FCS's would require the submission of a separate notification for each of the new uses. FDA believes that this approach will permit the agency to better manage its resources and its statutory obligations concerning the review of notifications for FCS's.

B. Notifications for Food Contact Substances: General

Proposed § 170.100 contains the general regulations for submitting a PMN. The agency is proposing in § 170.100(a)(1) that a PMN contain all the information described in proposed § 170.101. In addition, proposed § 170.100(a)(2) states that a notifier may incorporate by reference any information in FDA files that is available to the notifier. This would include publicly disclosable material and material that the submitter of the information has given the notifier permission to reference. Finally, proposed § 170.100(a)(3) requires that a notifier provide all relevant information in English. This latter requirement is comparable to the requirement in 21 CFR 171.1(a) for data submitted in a FAP.

Proposed § 170.100(b) describes the circumstances under which FDA may choose not to accept a PMN. Under proposed § 170.100(b)(1) the submission of a PMN would be prohibited for any use of a substance that is already the subject of a regulation in 21 CFR parts 173 through 189. Under proposed § 170.100(b)(2) submission of a PMN would be prohibited for any use of a substance that is the subject of an exemption under the threshold of regulation process in § 170.39. Authorizations under section 409(b) of the act and exemptions under § 170.39 authorize the use of FCS's without regard to the manufacturer of the substance. Thus, a notification for a use already permitted by a regulation or an exemption would be redundant, and the review of such a notification would be

an inefficient use of agency resources. Moreover, such a notification could not be exclusive to the notifier and is therefore inconsistent with the FDAMA amendment to the statute. Therefore, FDA believes that it is appropriate to prohibit submission of a notification for a use of an FCS that is already permitted by a regulation or by an exemption. However, the agency requests comments regarding the appropriateness of FDA accepting PMN's for uses permitted by existing regulations or threshold of regulation (TOR) exemptions.

Section 409(h)(3)(B) of the act authorizes FDA to issue regulations identifying the circumstances in which a FAP shall be required to provide adequate assurance of safety regarding the use of an FCS. Section 409(h)(3)(B) of the act directs FDA to consider criteria such as the probable consumption of the FCS and its potential toxicity in identifying when a petition shall be required.

Based upon the information currently available, FDA believes that nearly all uses of FCS's would be the subject of PMN's. However, FDA believes there are circumstances in which submission and review of a FAP would be needed to assure safety. Therefore, the agency is proposing in § 170.100(c) a regulation to define the limited circumstances in which a petition would be required. The proposed regulation also provides that if the agency is consulted prior to submission and determines that a notification is more appropriate, a petition would not be required even under the circumstances described in proposed § 170.100(c). Proposed § 170.100(c) lists two circumstances that FDA currently believes should presumptively require the submission of a FAP. These circumstances are as follows: (1) When the use of the FCS will increase the cumulative dietary concentration to the FCS from food uses to a level greater than 1 part per million (ppm) (3 mg/person/day) or, in the case of a biocide, to a level greater than 200 parts per billion (ppb) (0.6 mg/person/day); and (2) when there exists one or more bioassays on the FCS that the agency has not already reviewed and such studies are not clearly negative for carcinogenicity.

Historically, FDA has based its recommendations for toxicity data to support the safe use of food additives on the estimated intake of the food additives. As a general rule, higher estimated intakes of substances in the diet pose both an increased risk of toxicity and a wider range of potential toxic effects. The maximum levels of cumulative dietary concentration identified above are levels at which the agency has historically requested more comprehensive toxicity testing in order to address a substance's potential to induce diverse toxic effects. To address the risk of these effects, FDA has asked for longer term toxicity studies and toxicity studies that measure a wider variety of toxic endpoints. The agency believes that this approach is sound, in that it has ensured the safety of additives permitted in the food supply. Thus, FDA continues to believe that uses of FCS's that have the potential for inducing diverse toxic effects of consequence to human health generally require longer term and more specialized toxicity testing to support their safe use. Where such toxicity testing is needed, the agency believes that submission, review, and approval of a food additive petition is appropriate because the petition process will afford FDA the time necessary to review the more extensive toxicity data package.

FDA has tentatively concluded that a lower dietary concentration cutoff for PMN's for biocides is appropriate for substances that are toxic by design. Biocides are a class of FCS's that have the potential to raise safety concerns because their intended technical effect is microbial toxicity. Because of this expectation of greater toxicity for biocides, FDA has historically requested longer term and specialized toxicity testing for biocides at a dietary concentration of 200 ppb (0.6 mg/person/day), rather than the 1 ppm (3 mg/person/day) level that would apply to most other FCS's. Consistent with FDA's testing recommendations, FDA is proposing in § 170.100(c)(1) that, for biocides, a petition be required where the maximum cumulative dietary concentration level is 200 ppb. FDA intends that this lower cut-off level would apply to substances used as FCS's primarily for their antimicrobial or fungicidal effects.

The use of carcinogens as food additives is prohibited by the food additives anti-cancer clause in section 409(c)(3)(A) of the act (the so-called Delaney clause). FDA believes that, if data exist that may demonstrate that an FCS is carcinogenic, a thorough review of such data is appropriate and necessary to adequately assure safety and properly administer the statute. Therefore, in proposed § 170.100(c)(2), FDA is proposing to require that the proposed use of an FCS be the subject of a petition when a bioassay on the FCS has not been reviewed by the agency and is not clearly negative for carcinogenicity.

FDA's current view is that in some situations where exposure exceeds 1 ppm (3 mg/person /day) or in the case of biocides, 200 ppb (0.6 mg/person/day)), the agency's concerns about potential toxicity may be alleviated by other factors, and thus, a notification may be acceptable. For example, if the cumulative estimated daily intake (CEDI) is greater than 1 ppm (3mg/person/day) but the agency has established an applicable acceptable daily intake (ADI) for the substance that is greater than the CEDI, then a notification would likely be acceptable. FDA expects to make publicly available a database of ADI's and CEDI's for regulated, exempted, and notified FCS's to assist potential notifiers in preparing notifications and petitions for FCS's. Based on the above, FDA is proposing that in the situations described in proposed § 170.100(c), a petition would be required unless FDA determines that a petition is not necessary to adequately assure safety even though the criteria of § 170.100(c)(1) or (c)(2) are met. Although sponsors are not required to consult with the agency prior to submitting either a petition or a notification, FDA strongly encourages presubmission discussion of uses that fall within the bounds of those circumstances defined in proposed § 170.100(c).

In order for FDA to be able to contact a notifier to provide an opportunity for the notifier to respond to agency's concerns regarding a PMN, the agency must have current information on the person for whom the notification is effective. Therefore, under proposed § 170.100(d), all notifiers would be required to inform FDA of any change in address.

C. Information Required in a Premarket Notification for an FCS

The FDAMA amendments require that an FCS meet the safety standard for food additives generally that is set out in section 409(c)(3)(A) of the act. Under section 409(h)(1) of the act, a notification shall include the notifier's determination that the intended use of the FCS is safe under the standard of section 409(c)(3)(A), as well as the data and information that forms the basis of such determination and any information required by regulation to be submitted. In light of this safety standard, FDA has tentatively concluded that the information in a premarket notification should be comparable to that required in a FAP for the same use. In addition, because of the short review period for PMN's, FDA is proposing to require in proposed § 170.101(a) that the notifier submit a comprehensive discussion of the data and information in the notification that forms the basis of the notifier's determination that the FCS is

safe. Under proposed § 170.101(a)(1), a discussion is comprehensive if it addresses all safety data in the notification. Although the discussion of every study or test need not be exhaustive, a notifier should include a thorough discussion of safety data that are important to the determination of safety. The notifier should also discuss in detail the notifier's basis for discounting or disregarding any data. To ensure a balanced evaluation of all existing data, FDA is also proposing to require in proposed § 170.101(a)(2) that the notifier address in the comprehensive discussion any information that appears inconsistent with the notifier's determination that the use of the FCS is safe. Under this proposed system, if FDA determines that a notifier's discussion is not sufficiently comprehensive to show that the notifier has considered all relevant data and information, the agency would object to the notification on the basis that the notification does not include all required information.

Proposed § 170.101(b) would require the notifier to submit all data and information relevant to the safety determination for the intended use of the FCS. This requirement is comparable to the requirement in entry E. of the form in 21 CFR 171.1(c) for FAP's concerning detailed data derived from appropriate animal and other biological experiments related to the safety of the additive be submitted in a FAP. Under proposed § 170.101(b), notifiers would be required to submit to FDA all primary biological and chemical data and information relevant to the safety of the intended use of the FCS. For example, notifications would include the primary data from relevant toxicity studies and from migration tests, including validation data. To assist notifiers in determining which data are relevant to the safety determination, in the **Federal Register** of November 12, 1999 (64 FR 61648), FDA announced the availability of two guidance documents on the chemistry and toxicology information recommended for inclusion in PMN's. In addition, FDA is announcing elsewhere in this issue of the **Federal Register** the availability of an administrative guidance document relating to the preparation of PMN's. These guidance documents include general recommendations that will help notifiers to satisfy the requirements of proposed § 170.101(b). For special circumstances not addressed in the guidance, notifiers are encouraged to consult with the agency prior to submitting a notification.

Proposed § 170.101(c) would require that all nonclinical laboratory studies submitted in a premarket notification be performed under good laboratory practices (GLP's) and include, for each study, a signed statement that the study has been performed under GLP's (proposed § 170.101(c)(1)) or a statement identifying the deviations from GLP's that occurred along with an explanation of the reasons for the deviations (proposed § 170.101(c)(2)). This section is comparable to § 171.1(k) (21 CFR 171.1(k)) for FAP's and would ensure that data submitted in support of the safety of the use of an FCS meet appropriate minimum technical standards.

In addition, proposed § 170.101(c)(3) would require that the data in each study conducted since 1978 but not conducted under GLP's be validated by an independent third party prior to submission to FDA. Finally, proposed § 170.101(c)(3) would require a signed certification from such a data validator. FDA has tentatively concluded that the requirement that such data be validated will ensure the reliability of data submitted in support of the safety of the use of an FCS. FDA currently believes that, because of the short time period for the review of notifications, it is necessary that data be validated in advance of submission to FDA.

Under the National Environmental Policy Act (NEPA), FDA must consider the environmental impact of its actions; the effect of this obligation is that for covered actions, either an environmental assessment or a claim of categorical exclusion is required.

In view of this NEPA obligation, FDA is taking two actions. First, in the **Federal Register** of May 11, 2000, FDA published a direct final rule (64 FR 30352) amending the agency's regulations in part 25 (21 CFR part 25), and a companion Notice of Proposed Rulemaking (65 FR 30366) proposing to amend the regulations in part 25. Specifically, the direct final rule amended, and the companion proposal proposed to amend, part 25 by adding to the list of those actions that require an environmental assessment in § 25.20 allowing a notification submitted under section 409(h) of the act to become effective, and by expanding the existing categorical exclusions in § 25.32(i), (j), (k), (q), and (r) to include allowing a notification submitted under section 409(h) of the act to become effective. This will allow notifiers of FCS's to claim the categorical exclusions now available to sponsors of other requests for authorization of FCS's. Second, as part of this rulemaking, FDA is proposing in § 170.101(d) that if the environmental component of a notification is missing or deficient under § 25.40, the agency will not accept the notification for review. In cases where the agency does not accept a notification based on deficiencies in environmental information, FDA expects to inform the notifier in writing within 30 days of receipt of the submission.

In response to the March 1999 public meeting, FDA received comments requesting that FDA consider incorporating standard forms in the requirements for information in PMN's. Although FDA currently believes that forms cannot replace a comprehensive discussion of the information in the notification or a discussion of the basis for a notifier's determination of safety, FDA tentatively agrees that forms may be useful in preparing and reviewing PMN's. Therefore, FDA is proposing in § 170.101(e) to require the submission of FDA Form No. 3480 with all notifications for FCS's. FDA expects to make this form available via the agency's internet site (http://vm.cfsan.fda.gov). FDA Form No. 3480, as well as FDA Form No. 3479 (see section III of this document), are undergoing review by the Office of Management and Budget as part of the paperwork reduction analysis (see section VII below) for this proposed rule.

D. Confidentiality of Information in a Premarket Notification for an FCS

Section 409(h)(4) of the act prohibits FDA from publicly disclosing any information in a PMN for 120 days after submission of the PMN to FDA. FDA is proposing to codify in § 170.102(a) the prohibition against disclosure of information in a notification. FDA currently believes that the intent of section 409(h)(4) of the act is to prevent the agency from disclosing information in a notification prior to completion of the agency's review. Therefore, FDA is proposing to add § 170.102(b) which provides that the information in a notification that is withdrawn within 120 days after receipt, and before the agency has completed its review, will not be publicly available. Similarly, FDA believes that the agency's conclusion regarding a notification should be publicly available at the time such conclusion is reached. Therefore, FDA is proposing in § 170.102(c) to provide that FDA's conclusion regarding a notification would be available at the time the agency's review is completed. However, FDA does not expect to actively disclose its conclusion regarding a notification; rather, FDA anticipates providing this information to

persons who contact the agency (i.e., by telephone, letter, or e-mail) after the conclusion of FDA's review.

The agency is planning to establish a publicly available inventory of effective PMN's (discussed below). FDA has tentatively concluded that the inventory will include the information necessary to describe adequately the substance that is the subject of the notification and the use of that substance for which the notification is effective. Such information may include, but will not necessarily be limited to, the complete chemical identity of the FCS, the maximum use level in food contact materials, any limitations on the types of food that may contact materials containing the substance, and limitations on time and temperature conditions of use for the material containing the substance. FDA believes that the foregoing information is necessary to describe adequately the circumstances under which a given notification is effective and that any claim to confidentiality of such information would hamper the agency's ability to adequately communicate which notifications have become effective. Therefore, as proposed, § 170.102(d) provides that by submitting a notification, the notifier waives any claim of confidentiality to the information required to describe adequately the FCS and the intended conditions of use that are the subject of the notification.

FDA is proposing to codify in § 170 102(e) the types of information in a PMN that will be publicly available once the statuatory 120-day review period is completed. The types of information listed in proposed § 170.102(e) are comparable to the types of information contained in or relating to an FAP that generally are publicly available under § 171.1 (h) either at the time the petition is filed or once the agency has rendered a decision on the petition. FDA has tentatively concluded that once the statuatory prohibition in section 409 (h) of the act against disclosure of information in a PMN expires, the disclosure of data and information in a PMN should be comparable to the disclosure of similar information when contained in an FAP. FDA specifically requests comments on all of the provisions of proposed § 170.102

E. Withdrawal Without Prejudice

Under proposed § 170.103, FDA is proposing that a notifier may withdraw a PMN at any time during the 120 days after receipt of the notification by FDA, if FDA has not completed its review. For the purpose of this section, FDA's review is complete when FDA has allowed 120 days to pass without objecting to the PMN, or when FDA has issued an objection letter. FDA tentatively believes that the outcome of the agency's review should be publicly available at the time it issues. As discussed above, FDA is proposing in § 170.102(c) to protect from public disclosure the information in a PMN withdrawn within 120 days of receipt by FDA.

F. Action on a Notification for an FCS

FDA currently plans to conduct an initial review of whether the basic informational items required under proposed § 170.101 are in a notification for an FCS. If, during this initial review, FDA finds that one of the elements required under proposed § 170.101 is missing, FDA believes that the agency should be able to decline to review such notification. Under proposed § 170.104(b)(1), FDA would inform a notifier in writing that a clearly deficient notification has not been accepted. In addition, if a notifier supplements a deficient notification before FDA informs the notifier in writing under proposed § 170.104(b)(1) then the date of receipt of the supplemental information would be the date of receipt of the notification for purposes of section 409(h)(1) of the act.

If FDA accepts a PMN, FDA expects to acknowledge receipt of the PMN in writing within 30 days of receipt (see proposed § 170.104(b)(2)). This acknowledgment would serve two purposes: First, the acknowledgment would inform the notifier of the date of receipt of the notification by FDA, and thereby the effective date of the notification if FDA does not object to the marketing of the substance; second, the acknowledgment would identify the substance and use that FDA understands are the subject of the notification. FDA intends to use this identity and use information in FDA's inventory of effective notifications (discussed below) if the notification becomes effective. If FDA determines during the course of review of a PMN that it is necessary to modify the description of the FCS or its intended use as conveyed in the acknowledgment letter, FDA intends to promptly inform the notifier of any such changes.

If, after reviewing a notification, FDA does not agree that the notifier has demonstrated that the substance is safe under the intended conditions of use, FDA would inform the notifier in writing that FDA objects to the marketing of the substance for the use that is the subject of the notification and would describe the basis for the objection. Under proposed § 170.104(c)(1), if FDA objects to a PMN, FDA will inform the notifier in writing. FDA has tentatively concluded that the date of the objection letter should be the date that the agency objects to the notification for the purposes of section 409(h)(2)(A) of the act, and has proposed such an arrangement in § 170.104(c)(1). FDA believes that this practice for objection dates will simplify management of the notification process. For purposes of clarity, FDA is also proposing in § 170.104(c)(2) to restate the statutory outcome that, if FDA objects to a notification during the 120-day review period, the notification would not become effective. Under section 409(a) of the act, in the absence of an effective notification, an FCS cannot be lawfully marketed.

FDA currently believes that, if information on which the notifier's determination of safety is based is inadequate to support a safety determination, the agency would object, under section 409(h)(2)(B) of the act, to the notification on the basis that the use of the FCS has not been shown to be safe under the standard of section 409(c)(3)(A). FDA currently believes that, if the notifier's discussion of the data supporting the safety of the use of the FCS is not comprehensive, the agency would consider the notification inadequate to support the safety of the intended use of the FCS and would object to the notification on that basis.

Section 409(h)(5)(A)(i) of the act states that the premarket notification program shall not operate in any fiscal year (FY) for which the program is not funded as described in section 409(h)(5). FDA currently believes that the agency must be able to object to a notification if the notification program ceases to operate before the end of the 120-day period after FDA's receipt of the notification in accordance with section 409(h)(5) of the act. Accordingly, proposed § 170.104(c)(3) would authorize FDA to object to a premarket notification on the basis that some portion of the 120-day review period occurs during a period while the PMN program is not operating. Proposed § 170.104(c)(3) would not, however, require FDA to object. For example, if FDA determines that it can complete its review of a PMN while the PMN program operates, the agency would not object to a notification solely on the basis of proposed § 170.104(c)(3).

Unlike the FAP process, there is no requirement under the PMN process that FDA publish either a filing notice or a final rule in the **Federal Register** in order to authorize the use of an FCS. Moreover, the statute does not require

FDA to issue a letter at the conclusion of the review of a notification, in contrast to the threshold of regulation process under § 170.39. No action by FDA is required for a notification to become effective 120 days after receipt by the agency. However, FDA has considered information provided by the public at the March 1999 public meeting and has tentatively concluded that issuing a letter identifying the notification and the date on which the notification became effective may be valuable in bringing the review process to closure. Such a letter could also clarify the identity or intended use of the FCS if there is a need to do so. Therefore, FDA's current plan is to reissue the acknowledgment letter and to add a statement regarding the date on which the notification became effective and to describe any changes in identity or use of the FCS. Because FDA is concerned that the issuance of a final letter for every PMN may become an administrative burden on the agency, the agency is not proposing to make issuance of such a letter a requirement.

In order to administer the PMN program efficiently, FDA has tentatively concluded that the agency should maintain a publicly available inventory of effective notifications. Such an inventory would permit both the regulated industry and the public readily to determine whether an effective notification exists for use of an FCS. As currently envisioned by the agency, the publicly available inventory would include such information as the identity of the substance, the notified use, the manufacturer identified in the notification, the effective date of the notification, and a tracking number identifying the notification. FDA expects to make the inventory of effective notifications available on the agency's Internet site (http://vm.cfsan.fda.gov). FDA is specifically requesting comments on the agency's plan for the inventory of effective notifications and on ways the agency may make the inventory most useful to the public.

As noted, section 409(h)(3)(A) of the act requires that the notification process be utilized for authorizing new uses of food contact substances except where the agency determines that a FAP is necessary to provide adequate assurance of safety or where FDA and a manufacturer or supplier agree that such manufacturer or supplier may submit a petition. FDA currently believes that there may be some instances where a codified regulation may be in the best interest of the public and the agency, and in such cases, the agency would agree to accept a petition. However, FDA should not be required to review both a petition and a notification for the same use of an FCS. Thus, proposed § 170.104(d) would provide that a premarket notification would be deemed withdrawn if FDA and a notifier agree under section 409(h)(3)(A) of the act that the notifier may submit a FAP proposing the approval of the FCS for the use described in the notification. FDA is also proposing to amend § 171.1(i)(1) to ensure that FDA is not required to file a FAP for the use of an FCS that, under section 409(h)(3)(A) of the act, may be the subject of a notification.

G. Determination That a Premarket Notification Is No Longer Effective

Section 409(i) of the act states that FDA shall by regulation prescribe the procedure by which the agency may deem a premarket notification to no longer be effective. If information becomes available that indicates that the use of an FCS that is the subject of an effective notification may no longer be considered safe, FDA believes that such information must be adequately addressed by the notifier for the notification to continue to be effective. Proposed § 170.105(a) states that FDA may determine that a PMN is no longer effective if the available information demonstrates that the use of an FCS is no longer safe. Proposed § 170.105(b) states that FDA would inform the notifier in writing of the agency's tentative conclusion that a notification is no longer effective, and would provide the basis for that conclusion. In addition, FDA will establish a timeframe for the notifier to respond to the agency's tentative conclusion. Under proposed § 170.105(b) the notifier would be given an opportunity to address FDA's safety concerns. Under proposed § 170.105(c), if the notifier is not able to address adequately FDA's concerns, FDA would publish a notice in the **Federal Register** stating the agency's conclusion that the notification is no longer effective. The date of such notice will be the date after which the notification shall no longer be effective. FDA has tentatively concluded that the agency's determination that a notification is no longer effective shall be the final agency action subject to judicial review (proposed § 170.105(d)).

III. Notifications for Formulations

As discussed above, in response to the March 1999 public meeting, the agency received comments requesting that the agency accept notifications for food contact substance formulations (NFCSF's). Such notifications would be distinct from notifications for FCS's in two ways. First, NFCSF's would be for a particular mixture of FCS's and would be for more than one FCS. Second, each of the substances in the formulation would already be authorized for its intended use in contact with food. Thus, FDA's evaluation of NFCSF's would be limited to a review of the basis for compliance with section 409 of the act.

Because each substance in an NFCSF would already be authorized for its intended use, such notifications would not be required under section 409 of the act. Nor does the act require FDA to implement and operate such a program. Comments in response to the March 1999 public meeting stated that such notifications would be useful for facilitating trade in both food contact materials and in food, if FDA would choose to accept these notifications under the PMN process. FDA also believes that acceptance and review of NFCSF's will aid the agency in monitoring compliance within the regulated industry and provide the agency with better information on the types of food contact materials in use. Therefore, FDA is proposing, in § 170.106(a), to accept NFCSF's where the notifier can establish that each of the components of the formulation is authorized for its intended use. However, FDA has serious concerns about the potential burden that accepting notifications for formulations could place on the agency. Therefore, proposed § 170.106(b) states that the agency may decline to accept NFCSF's by publishing a notice in the **Federal Register** stating that the agency does not have sufficient resources to review such notifications. FDA believes that this level of notice is appropriate because there is no statutory requirement for FDA to accept NFCSF's.

FDA's current view is that notifications for formulations would not require resubmission of the information supporting the safety of the intended use of each food contact substance in the formulation. FDA has tentatively concluded that a notifier for a formulation would ordinarily submit only a completed FDA Form No. 3479 and any additional information necessary to establish that the specific conditions of use in the formulation for each FCS are authorized. Also, in cases where the basis for compliance of an individual FCS in a formulation is an effective notification, a notifier would need to certify that he could rely on the notification cited. Therefore, under proposed § 170.106(c), FDA would require that a notification for a food contact substance formulation include a completed FDA Form No. 3479 and any additional information to establish that

each of the components of the formulation is authorized for its intended use. FDA is specifically requesting comments on proposed § 170.106.

IV. Transition Policy

At the time the premarket notification program began to operate, the agency had an inventory of pending FAP's for the use of FCS's. FDA also had an inventory of pending TOR exemption requests (submitted under § 170.39). FDA believes that nearly all of these petitions and exemption requests are for uses that would meet the criteria under proposed § 170.100 for premarket notification.

At any time that the PMN program is operational, a petitioner may withdraw a FAP or TOR request for the use of an FCS and resubmit the petition or request as a PMN. If a petitioner does not withdraw a petition and such petitioner submits a PMN for the same use, the petition would be deemed withdrawn under proposed § 171.7(c) for the use or uses described in the notification. In a letter dated October 25, 1999, FDA strongly encouraged petitioners and requesters under the threshold of regulation process to contact the agency prior to withdrawal of a petition or a TOR request to obtain specific guidance on conversion of the petition or request to a PMN. Finally, for some of the FAP's and TOR requests in the agency's inventory when the notification program began to operate, FDA was awaiting the submission of additional information that the agency has considered necessary to the safety determination. Any such information would be necessary to establish the safety of the intended use of the FCS if a petition or request were resubmitted as a notification.

V. Conforming Amendments

FDA is proposing several conforming amendments to the agency's regulations to help to administer the PMN process and to clarify the application of the food additive regulations to FCS's.

Section 20.100 cross-references regulations concerning the public availability of information in specific types of documents submitted to FDA. FDA is proposing to amend this section to cross-reference the regulations on the disclosure of information in PMN's under proposed § 170.102.

FDA is proposing to amend § 58.3 (21 CFR 58.3) to add PMN's to the list of types of submissions that the agency classifies as ''Applications for research or marketing permits.'' This amendment will make the appropriate provisions of the agency's GLP regulations applicable to PMN's.

FCS's that are the subject of PMN's will not be listed in the food additive regulations for their intended uses. Therefore, FDA proposes to amend §§ 174.5(d) and 179.25(c) (21 CFR 174.5(d) and 179.25(c)) to provide appropriate cross references for the use of an FCS that is the subject of an effective PMN.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on the following: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Food Contact Substances Notification System

Description: Section 409(h) of the act establishes a premarket notification process for FCS's. Section 409(h)(6) of the act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Section 409(h)(3) of the act requires that the notification process be utilized for authorizing the marketing of FCS's except where FDA determines that the submission and premarket review of a FAP under section 409(b) of the act is necessary to provide adequate assurance of safety. Section 409(h)(1) of the act requires that a notification include information on the identity and the intended use of the food contact substance and the basis for the notifier's determination that the food contact substance is safe under the intended conditions of use. Because section 409(h)(1) of the act references the general safety standard for food additives, the data in a PMN should be comparable to the data in a FAP. FDA is proposing regulations necessary to implement the premarket notification program which will largely replace the FAP process for those food additives that are food contact substances. The collection of information associated with notifications for new uses of FCS's under section 409 of the act has been previously announced for public comment in a notice published in the **Federal Register** of November 12, 1999 (64 FR 61648).

FDA is also proposing to require that a notification for a food contact substance include FDA Form No. 3480 ''Notification for New Use of a Food Contact Substance'' and a notification for a formulation of a food contact material include FDA Form No. 3479 ''Notification for a Food Contact Substance Formulation'' that will serve to summarize pertinent information in the notification. FDA Form No. 3480 was made available for public comment in the November 12, 1999, notice. FDA believes that these forms will facilitate both preparation and review of notifications since the forms will serve to organize information necessary to support the safety of the use of the FCS. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Description of Respondents: Manufacturers of food contact substances.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.106[2]	FDA 3479	200	4	800	2	1,600
170.101[3,7]	FDA 3480	200	1	200	25	5,000

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.101[4,7]	FDA 3480	55	2	110	120	13,200
170.101[5,7]	FDA 3480	45	2	90	150	13,500
170.101[6,7]	FDA 3480	16	1	16	150	2,400
Total						35,700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Notifications for a food contact substance formulation. These notifications require only FDA Form No. 3479 (''Notification for a Food Contact Substance Formulation'') to be filled out and documentation attached.
[3] Duplicate notifications for uses of food contact substances.
[4] Notifications for uses that would currently be the subject of exemptions under 21 CFR 170.39 or very simple FAP's.
[5] Notifications for uses that would currently be the subject of moderately complex FAP's.
[6] Notifications for uses that would currently be the subject of more complex FAPs.
[7] These notifications require the submission of FDA Form No. 3480 (''Notification for New Use of a Food Contact Substance'').

The above estimate is based on the types of submissions that FDA currently receives for food contact substances in the TOR and the FAP processes and the following assumptions and information:

- FDA estimates that the likely increase in PMN's over the number of FAP's and TOR requests will be approximately four times the highest recent influx of these submissions (50 and 54, respectively). This factor is based on an analysis of the number of companies producing various types of food contact substances and the types of food contact substances for which FAP's and TOR's are most commonly submitted to FDA.
- Based on input from industry sources, FDA estimates that the agency will receive approximately 800 notifications annually for food contact substance formulations.
- FDA also has included 200 expected duplicate submissions in the second lowest tier. FDA expects that the burden for preparing these notifications will primarily consist of the notifier filling out FDA Form No. 3480, verifying that a previous notification is effective, and preparing necessary documentation.
- Based on the amount of data typically submitted in FAP's and TOR requests, FDA identified three other tiers of PMN's that represent escalating levels of burden required to collect information.
- FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers based on input from industry sources.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding the information collection by August 14, 2000 to the Office of Information and Regulatory Affairs, OMB (address above), Attn: Desk Officer for FDA.

VII. Analysis of Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

1. The Need for Regulation

This notice proposes regulations that are needed to help implement the premarket notification process for food contact substances created by FDAMA. These premarket notifications will largely replace FAP's for food contact substances. In the petition process, FDA evaluates the safety of the proposed use of a food additive and, if FDA determines that the proposed use is safe, the agency issues a regulation authorizing the legal marketing of the product. Under the statute, FDA has an initial period of 90 days, which may be extended for an additional 90 days, in which to make a determination regarding the safety of the proposed use and publish an order stating the agency's determination. However, regardless of the time that actually passes after submission of a FAP, the FAP may not be legally marketed until FDA publishes an authorizing regulation. By contrast, the premarket notification provision of FDAMA requires FDA to object within 120 days to a manufacturer's notification that it intends to use a particular food contact substance for a particular use, or the substance may be legally marketed on the 121st day without issuance of a regulation.

This notice also proposes regulations to implement the statutory requirement that information in a PMN not be publicly disclosed before completion of FDA's review. Under the petition process, the publication in the **Federal Register** of the notice of filing for the petition permits competitors of the petitioner to learn about the new food contact substance before authorization. Disclosure of a manufacturer's intent to market a substance before authorization lowers the competitive advantage of a new product, since a food additive regulation authorizes anyone to market the substance for its intended use. Under section 409(h) of the act and the proposed rule, a notification will be effective for the manufacturer named in the notification only, thereby protecting the commercial intent of the manufacturers of the new food contact substance during the period of review, and permitting the manufacturer of the new food contact substance to market the substance first.

The implementing regulations propose binding criteria for the successful submission of notifications and a concrete framework for the resolution of routine questions or problems arising in the notification process. The notification process is more predictable than the

corresponding FAP process, because the notifier will have either an effective notification or FDA's objection within 120 days. The structure added by limited implementing regulations would enhance the predictability of that process and reduce the burden on all potential notifiers. Therefore, the proposed regulations implementing the statutory requirement for PMN's would help the agency to reduce delays in the marketing of new food contact substances. In the absence of the proposed rule, the agency would be less effective in achieving this goal.

In the economic analysis of the proposed rule, the agency will not separate the benefits and costs of the statute from the benefits and costs of the regulations helping to implement the statute. The regulations and the statute are complementary and will be assessed together.

2. Regulatory Options

FDA examined a range of regulatory options to demonstrate why the proposed action is most beneficial to the public. Not all of the options discussed below are currently legally available. FDA assesses options that are not legally available in order to elucidate its reasoning for the option that was chosen.

a. *No new regulatory activity.* No additional social costs or benefits are associated with this option. Section 409 of the act does not require FDA to issue regulations to implement the notification process for food contact substances except for regulations prescribing the procedure by which a notification may be deemed no longer effective (section 409(i)(3)). The notification process for food contact substances begins to operate when the budgetary requirements of section 409(h)(5) of the act are met whether or not FDA issues regulations.

If no regulations exist to govern the notification program when it begins to operate, FDA will operate the program through guidance alone. This situation would provide the most discretion for FDA to deal with individual notifications but would provide less predictability for industry. Less predictability would create additional burden on the industry to prepare and manage notifications for review.

As stated above, the proposed implementing regulations provide binding criteria for the successful submission of notifications and a concrete framework for the resolution of routine questions or problems arising in the notification process. The notification process is more predictable than the corresponding FAP process, because the notifier will have either an effective notification or FDA's objection within 120 days. The structure added by limited implementing regulations will enhance the predictability of that process and reduce the burden on all potential notifiers. Furthermore, if the agency continued to rely on the current FAP procedure to approve food contact substances, there could be delays in meeting consumer demand when the agency's evaluation has not been completed within a predictable time; these delays could represent potentially significant avoidable costs. This unpredictability discourages new products when the food contact substance manufacturers do not believe their products can be brought to market within a reasonable time. When products are not brought to market, the public bears a social cost in terms of lost consumer satisfaction from the lack of desirable products. Although the public cost from new products not being brought to market are mostly unseen and are not measurable, they may be large.

b. *Modification of the petition process to require automatic authorization at the end.* Although this option is not legally available, the public might have benefited if the current petition process were modified to require automatic authorization at the end of a specified review period. The period of evaluation for food contact substance petitions could be extended to 120 days, with automatic authorization granted for petitions that are not reviewed during this period. Extending the review period would provide the agency with additional time to review each petition and the requirement of automatic agency authorization at the end of the review period would create reliable expectations for petitioners. However, extending the period of evaluation would not address all of the problems that petitioners encounter in the current process. This option neglects the circumstance that certain information may be disclosed to competitors during the review process.

c. *Stricter requirements for data submission.* The agency might have proposed to require that food contact substances meet stricter requirements for data submission than those it is proposing. For example, FDA might require additional validation for all data that form the basis of the determination that the food contact substance is safe for the intended use. The agency did not choose this option because additional data requirements would impose a cost by potentially delaying the introduction of beneficial substances.

d. *Deregulation—no requirement for a petition or a notification.* Congress could legislate to dispense with the approval of new food contact substances through either petitions or notifications. The objection to this option is that the agency's review and authorization of food contact substances protects the public from harmful substances that might otherwise be introduced into the food supply and reduces the costs of private monitoring of the food supply. Protection in this context means that the agency requires that manufacturers of products under review by FDA demonstrate a reasonable certainty of no harm from the intended use of the product.

With deregulation, consumers bear the risks when producers sell products that do not meet the regulatory standard of reasonable certainty of no harm. If the approval of new food contact substances were withdrawn, consumers would have to monitor the safety of the substances in the food supply. If products cause harm, consumers would have to rely on the tort system for redress. Consumers would have to prove that a harm was linked to the food contact substance based on a standard that might vary by jurisdiction or at the whim of a jury. Furthermore, proving the link between the substance and the harm could be extremely difficult. Private markets operate within the framework of legal institutions. The tort system of the common law evolved, in part, to provide remedies to injuries suffered in transactions in private markets. For instance, under this system, if a defective product injures someone, then the injured person may recover damages from the producer of the defective product. The recovery of damages requires the injured person to prove that his injuries were caused by the producer's product. Regardless of the legal standard chosen (negligence, warranty, or strict liability) the injured person must be able to link his injury to the specific product of a specific producer. Because legal proceedings are always retrospective and must have occurred after the plaintiff consumer has suffered an injury, the social cost under the tort system is the cost of the harm caused to the plaintiff and the cost of the legal proceedings.

In most instances, consumers experiencing illness or other harm from food consumption do not recognize the illness as foodborne or are unable to link the illness to consumption of a particular food. This inability to connect illness and food or food contact substances exists because many symptoms do not occur immediately after consumption of the product. Many

consumers are never compensated, and in practice, the tort system is rarely used to remedy the harm that comes from unsafe foods or food additives. Therefore, the costs of private monitoring and enforcement of safety using the tort system in an unregulated market are probably substantially greater than the social costs of regulatory enforcement and the additional research costs needed to demonstrate with reasonable certainty that products are safe.

3. Benefits

The benefits from the change to premarket notifications come from the increased innovation in the food contact substance market. Consumers want new and better food contact substances (or their properties) and receive benefits from them in the form of increased satisfaction. Although new substances will (on average) generate monetary benefits that exceed monetary costs—if not, new substances would not be introduced—it is difficult to place a monetary value on the full increase in consumer satisfaction from better food contact substances in the future. FDA therefore did not attempt to directly measure the increased consumer satisfaction arising from greater innovation in food contact substances. Instead, the agency estimated the benefits indirectly by the increase in innovation. FDA measured the benefits from the change to premarket notifications as the expected increase in the annual number of new notifications after the change. More product notifications to the agency imply more innovation, which in turn implies better products and greater consumer satisfaction.

Determining the benefits without regard for the congressional requirement to change regimes, although it ignores the rationale and legal authority for the change, provides a simple measure of the consequences of the change to the system of premarket notifications for new food contact substances. The increase in notifications, however, may overstate innovation because: (1) Not all notifications will be for new products and (2) the new regime will require each manufacturer to submit a notification to obtain marketing approval so some duplication of firm and agency resources might occur when different manufacturers produce the same substances. Thus, the estimated benefit due to innovation represents a maximum.

The agency estimated that the likely increase in submissions will be approximately four times the highest recent number of annual submissions for food contact substances (50 FAP's and 54 TOR submissions). Thus, for fiscal year (FY) 2000, FDA estimates that 416 premarket notifications will be submitted (4 x 50 + 4 x 54). As explained above, the agency has not attempted to place a monetary value on the benefits from these submissions.

4. Costs

The costs of the proposed rule are the costs incurred by firms that notify the agency of a new substance, but would not have had to under the previous regime. The firms that will bear this cost manufacture products identical to those that have already been through the notification process. These firms would formerly have been able to avoid the regulatory process altogether.

The agency used the following calculation:

Cost = (Number of Notifications) X (Hours/Notification) X (Hourly Rate to Prepare a Notification) + (Number of Notifications) X (Average Cost for Data Development)

The agency determined the expected number of notifications for seven categories of notifications for those firms that are expected to make substances identical to those for which notifications have been received, the number of hours required to prepare the notification for each category, and the estimated average hourly cost to prepare the notification. In addition the agency estimated the average cost of developing the data for each type of submission.

The total number of FAP's and TOR's received in FY 1998 and that would be affected by the change in regimes was 102. Based on petition data, these 102 were divided between petitions for components of food contact materials and petitions for substances used to manufacture food which do not have an intended effect in the food as consumed. The burden of the data collection for FAP's varies with the type of petition submitted. The following are the agency's estimates of the information collection burden for FAP's and TOR's.

A TOR requires the least amount of time for the collection of information: approximately 88 hours per submission. Forty-nine TOR's were received in FY 1998, resulting in a burden of 4,664 hours.

Category A. A simple indirect additive petition with minimal testing requirements (collection of identity information, genetic toxicity testing and administrative details) requires approximately 120 hours per petition. Sixteen such petitions of this type were received in FY 1998, resulting in a burden of 1,920 hours. In addition, the average data collection costs for such petitions is about $12,500, resulting in a total dollar burden for data collection of $200,000 for FY 1998.

Category B. An average indirect additive petition consisting of analytical work, 90-day feeding studies, toxicological review of study data, and internal review and the drafting of the petition, requires approximately 150 hours per petition. Twenty-two such petitions were received in FY 1998, resulting in a burden of 3,300 hours. In addition, the average data collection costs for such petitions is about $350,000, resulting in a total dollar burden for data collection of $7,700,000 for FY 1998.

Category C. For an indirect additive petition with complex analytical work, the estimated time requirement per petition is approximately 150 hours. Eleven such petitions were received in FY 1998, resulting in a burden of 1,650 hours. In addition, the average data collection costs for such petitions is about $375,000, resulting in a total dollar burden for data collection of $4,125,000 for FY 1998.

Category D. A petition for a major new component of food packaging, involving long-term feeding studies, toxicology review, analytical work, and administrative details, requires more hours and a larger dollar investment for data development. FDA does not expect to accept such petitions as notifications.

Category E. A simple petition for a secondary direct food additive with minimal testing requirements (collection of identity information, minimal toxicity testing, analytical work and administrative details) requires approximately 120 hours per petition. One such petition was received in FY 1998, resulting in a burden of 120 hours. In addition, the average data collection costs for such petitions is about $12,500, resulting in a total dollar burden for data collection of $12,500 for FY 1998.

Category F. An average secondary direct additive petition consisting of analytical work, 90-day feeding studies, toxicological review of study data, and internal review and the drafting of the petition, requires approximately 150 hours per petition. Two such petitions were received in FY 1998, resulting in a burden of 300 hours. In addition, the average data collection costs for such petitions is about $350,000, resulting in a total dollar burden for data collection of $700,000 for FY 1998.

Furnishing the information required even in a simple indirect additive petition requires a team of professional employees, which may include toxicologists, chemists, environmental scientists, and lawyers. According to information provided by industry trade

associations, the collection of information, analytical work, toxicological review and administrative details involved in such a petition (Category A) average about 120 hours. In addition, such a petition requires an average of $12,500 for data development. Assuming that the aggregate professional hourly cost is $90, then the cost for submitting a simple petition is $10,800 (calculated by multiplying the hourly cost and the total hours) + $12,500 (for data development), for a total cost of $23,300.

The following summaries list the TOR and petition categories and the cost for each, assuming an aggregate professional hourly cost of $90.

TABLE 2.—CATEGORIES OF FOOD CONTACT SUBSTANCE SUBMISSIONS (CURRENT)

Submission Type	No. of Submissions	Total Hours	Cost of Hours	Other Costs
Threshold of regulation	49	4,664	419,760	0
Category A	6	1,920	172,800	200,000
Category B	22	3,300	297,000	7,700,000
Category C	11	1,650	148,500	4,125,000
Category D	0	0	0	0
Category E	1	120	10,800	12,500
Category F	2	300	27,000	700,000
Totals		11,954	1,075,860	12,737,500

If, in a given fiscal year the expected number of PMN's has the same proportion of categories as does the FY 1998 petitions and TOR's, then the agency expects:

TABLE 3.—CATEGORIES OF FOOD CONTACT SUBSTANCE SUBMISSIONS (PROJECTED)

Submission Type	No. of Notifications	Total Hours	Cost of Hours	Other Costs
Threshold of regulation	201	17,688	1,591,920	0
Category A	66	7,920	712,800	825,000
Category B	91	13,650	1,285,000	31,850,000
Category C	46	6,900	621,000	17,250,000
Category D	0	0	0	0
Category E	4	480	43,200	50,000
Category F	8	1,200	108,000	2,800,000
Totals		47,838	4,361,920	52,775,000

FDA expects approximately 50 percent of new notifications to be duplicates of PMN's submitted for products that would have required only one authorization under the old regime. Comparable products that could have used authorizations for another firm's product now require separate authorizations. Therefore, 50 percent of the expected total cost is the social cost imposed on the industry because of the change in regimes, for a total expected social cost of $26,387,500. As with the estimate of benefits above, this estimate of social cost represents a maximum cost since duplicate notifications may not require development of new scientific data.

5. Summary of Benefits and Costs

The social benefits of the proposed change in regime are from new product innovation. The agency estimates that four times the current number of petitions and TOR's will be introduced into the market, for a total of 416. The social costs from the change in regimes are the costs to submit duplicate notifications. The agency estimates that 50 percent of the total will be duplicate notifications for a maximum total social cost of $26,387,500.

B. Initial Regulatory Flexibility Analysis

1. Introduction

FDA has examined the economic implications of these proposed rules as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lesson the economic effect of the rule on small entities.

2. Economic Effects on Small Entities

We were unable to estimate how many small entities will be affected by this proposed regulation, because the universe of affected small entities might include any entities with a new idea. Past practice may not be a useful guide for estimating how many future entities will be affected. Some of these firms will now have to submit a PMN, when in the past they would not have had to. Because they will have to make a submission, the cost may act as a barrier and discourage them. On the other hand, firms that might not have submitted an application because the regime did not protect their ideas from copying, will now have some protection for their ideas by virtue of the new regime and thus be more likely to submit a PMN. We believe the net affect will be to encourage more innovation as reflected by more notifications.

3. Regulatory Relief

Because some small firms are expected to be adversely affected by the proposed rule, options for regulatory relief, such as small business exemption, need to be addressed. The benefit of this option is that small businesses would not incur an additional cost. The drawback is that small firms could then copy and distribute themselves the substances being reviewed in response to the marketing submission of a competitor, creating disincentives for new substance development by rival firms.

4. Description of RecordKeeping and Reporting

There are no additional recordkeeping requirements for the proposed rule.

5. Summary

FDA estimates that there will be no additional direct costs to small businesses because of this rule. If small business entities determine that the costs of notification outweighed the

benefits, the small business entities could rely on existing authorized food contact substances.

C. Unfunded Mandates and Congressional Review

Section 1531(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), defines a significant rule as a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year. FDA has determined that this rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule is not a major rule for the purpose of congressional review.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

IX. Comments

Interested persons may, on or before September 26, 2000, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule, except that comments regarding the information collection provisions should be submitted on or before August 14, 2000. 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 may be seen in the Dockets Management Branch. (address above above) between 9 a.m. and 4 p.m., Monday through Friday.

X. 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.

1. FDA Form No. 3479 ''Notification for a Food Contact Substance Formulation,'' Rev. 9/99.

2. FDA Form No. 3480 ''Notification for a New Use of A Food Contact Substance,'' Rev. 5/00.

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 58

Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR 171

Administrative practice and procedure, Food additives.

21 CFR Part 174

Food additives, Food packaging.

21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs it is proposed that 21 CFR parts 20, 58, 170, 171, 174, and 179 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264n, 265, 300u–300u–5, 300aa–1.

2. Section 20.100 is amended by adding paragraph (c)(42) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(42) Premarket notifications for food contact substances, in § 170.102 of this chapter.

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

3. The authority citation for 21 CFR part 58 continues to read as follows:

Authority: 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b-360f, 360h-360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b-263n.

4. Section 58.3 is amended by adding paragraph (e)(23) to read as follows:

§ 58.3 Definitions.

* * * * *

(e) * * *

(23) A premarket notification for a food contact substance, described in part 170, subpart D, of this chapter.

* * * * *

PART 170—FOOD ADDITIVES

5. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

6. Section 170.3 is amended by revising paragraph (e)(2), and adding paragraph (e)(3) to read as follows:

§ 170.3 Definitions.

* * * * *

(e)(1) * * *

(2) *Uses of food additives not requiring a listing regulation.* Use of a substance in a food contact article (e.g., food-packaging or food-processing equipment) whereby the substance migrates, or may reasonably be expected to migrate, into food at such levels that the use has been exempted from regulation as a food additive under § 170.39, and food contact substances used in accordance with a notification submitted under section 409(h) of the act that is effective.

(3) *A food contact substance* is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

* * * * *

7. Subpart D, consisting of §§ 170.100 through 170.106 is added to part 170 to read as follows:

Subpart D—Premarket Notifications

Sec.

Subpart D—Premarket Notifications

§ 170.100 Submission of a premarket notification for a food contact substance (PMN) to the Food and Drug Administration (FDA).

(a) A PMN is effective for the food contact substance manufactured or prepared by the manufacturer or supplier identified in the PMN submission. If another manufacturer or supplier wishes to market the same food contact substance for the same use, that manufacturer or supplier must also submit a PMN to FDA.

(1) A PMN must contain all of the information described in § 170.101.

(2) A PMN may incorporate by reference any information in FDA's files provided that the notifier is authorized to reference the information. The PMN should include information establishing that the notifier is authorized to reference information in FDA's files.

(3) Any material submitted in or referenced by a PMN that is in a foreign language must be accompanied by an English translation verified to be complete and accurate.

(b) FDA may choose not to accept a PMN for either of the following:

(1) A use of a food contact substance that is the subject of a regulation in parts 173 through 189 of this chapter; or

(2) A use of a food contact substance that is the subject of an exemption under the threshold of regulation process described in § 170.39.

(c) A petition must be submitted under § 171.1 of this chapter to authorize the safe use of a food contact substance in either of the following circumstances, unless FDA agrees to accept a PMN for the proposed use.

(1) The use of the food contact substance increases the cumulative dietary concentration to a certain level. For a substance that is a biocide (e.g., it is intended to exert microbial toxicity), this level is equal to or greater than 200 parts per billion in the daily diet (0.6 milligram (mg)/person/day). For a substance that is not a biocide, this level is equal to or greater than 1 part per million in the daily diet (3 mg/person/day); or

(2) There exists a bioassay on the food contact substances, FDA has not reviewed the bioassay, and the bioassay is not clearly negative for carcinogenic effects.

(d) A notifier must keep a current address on file with FDA.

(1) The current address may be either the notifier's address or the address of the notifier's agent.

(2) FDA will deliver correspondence to the notifier's current address.

§ 170.101 Information in a premarket notification for a food contact substance (PMN).

A PMN must contain the following:

(a) A comprehensive discussion of the basis for the notifier's determination that the use of the food contact substance is safe. This discussion must:

(1) Discuss all information and data submitted in the notification; and

(2) Address any information and data that may appear to be inconsistent with the notifier's determination that the proposed use of the food contact substance is safe.

(b) All data and other information that form the basis of the notifier's determination that the food contact substance is safe under the intended conditions of use. Data must include primary biological data and chemical data.

(c) A good laboratory practice statement for each nonclinical laboratory study that is submitted as part of the PMN, in the form of either:

(1) A signed statement that the study was conducted in compliance with the good laboratory practice regulations under part 58 of this chapter; or

(2) A brief signed statement listing the reason(s) that the study was not conducted in compliance with part 58 of this chapter.

(3) Data from any study conducted after 1978 but not conducted in compliance with part 58 of this chapter must be validated by an independent third party prior to submission to the Food and Drug Administration (FDA), and the report and signed certification of the validating party must be submitted as part of the notification.

(d) Information to address FDA's responsibility under the National Environmental Policy Act, in the form of either:

(1) A claim of categorical exclusion under § 25.30 or § 25.32 of this chapter; or

(2) An environmental assessment complying with § 25.40 of this chapter.

(e) A completed and signed FDA Form No. 3480.

§ 170.102 Confidentiality of information in a premarket notification for a food contact substance (PMN).

(a) During the 120-day period of the Food and Drug Administration (FDA) review of a PMN, FDA will not publicly disclose any information in that PMN.

(b) FDA will not publicly disclose the information in a PMN that is withdrawn prior to the completion of FDA's review.

(c) Once FDA completes its review of a PMN, the agency will make its conclusion about the PMN publicly available. For example, if FDA objects to a notification 90 days after the date of receipt, the agency would make available its objection at that time.

(d) By submitting a PMN to FDA, the notifier waives any claim to confidentiality of the information required to adequately describe the food contact substance and the intended conditions of use that are the subject of that PMN.

(e) The following data and information in a PMN are available for public disclosure, unless extraordinary circumstances are shown, on the 121st day after receipt of the notification by FDA, unless the PMN is withdrawn under § 170.103.

(1) All safety and functionality data and information submitted with or incorporated by reference into the notification. Safety and functionality data include all studies and tests of a food contact substance on animals and humans and all studies and tests on a food substance for establishing identity, stability, purity, potency, performance, and usefulness.

(2) A protocol for a test or study, unless it is exempt from disclosure under § 20.61 of this chapter.

(3) A list of all ingredients contained in a food contact substance, excluding information that is exempt from disclosure under § 20.61 of this chapter. Where applicable, an ingredient list will be identified as incomplete.

(4) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is exempt from disclosure under § 20.61 of this chapter.

(5) All correspondence and written summaries of oral discussions relating to the notification, except information that is exempt for disclosure under § 20.61.

(6) All other information not subject to an exemption from disclosure under subpart D of part 20 of this chapter.

§ 170.103 Withdrawal without prejudice of a premarket notification for a food contact substance (PMN).

A notifier may withdraw a PMN without prejudice to a future

submission to the Food and Drug Administration (FDA) if FDA has not completed review of the PMN. For the purpose of this section, FDA's review is completed when, FDA has allowed 120 days to pass without objecting to the PMN or FDA has issued an objection letter.

§ 170.104 Action on a premarket notification for a food contact substance (PMN).

(a) If the Food and Drug Administration (FDA) does not object to a PMN within the 120-day period for FDA review, the PMN becomes effective.

(b) In order for the 120-day review period to begin FDA must accept that notification.

(1) If any element required under § 170.101 is missing from a PMN, then FDA will not accept that PMN and FDA will send a PMN nonacceptance letter to the notifier. If the notifier submits the missing information before FDA sends a PMN nonacceptance letter, the date of receipt of the PMN will become the date of receipt of the missing information.

(2) If FDA accepts a PMN, then FDA will acknowledge in writing its receipt of that PMN.

(c) Objection to a PMN:

(1) If FDA objects to a PMN, then FDA will send a PMN objection letter. The date of the letter will be the date of FDA's objection for purposes of section 409(h)(2)(A) of the act.

(2) If FDA objects to a PMN within the 120-day period for FDA review, the PMN will not become effective.

(3) FDA may object to a PMN if any part of FDA's 120-day review occurs during a period when this program is not funded as required in section 409(h)(5) of the act.

(d) If FDA and a notifier agree that the notifier may submit a FAP proposing the approval of the food contact substance for the use in the notifier's PMN, FDA will consider that PMN to be withdrawn by the notifier on the date the petition is received by FDA.

§ 170.105 The Food and Drug Administration's (FDA's) determination that a premarket notification for a food contact substance (PMN) is no longer effective.

(a) If data or other information available to FDA, including data not submitted by the notifier, demonstrate that the intended use of the food contact substance is no longer safe, FDA may determine that the authorizing PMN is no longer effective.

(b) If FDA determines that a PMN is no longer effective, FDA will inform the notifier in writing of the basis for that determination. FDA will give the notifier an opportunity to show why the PMN should continue to be effective and will specify the time that the notifier will have to respond.

(c) If the notifier fails to respond adequately to the safety concerns regarding the notified use, FDA will publish a notice of its determination that the PMN is no longer effective. FDA will publish this notice in the **Federal Register**, stating that a detailed summary of the basis for FDA's determination that the PMN is no longer effective has been placed on public display and that copies are available upon request. The date that the notice publishes in the **Federal Register**, is the date on which the notification is no longer effective.

(d) FDA's determination that a PMN is no longer effective is final agency action subject to judicial review.

§ 170.106 Notification for a food contact substance formulation (NFCSF).

(a) In order for the Food and Drug Administration (FDA) to accept an NFCSF, any food additive that is a component of the formulation must be authorized for its intended use in that NFCSF.

(b) FDA may publish a notice in the **Federal Register** stating that the agency has insufficient resources to review NFCSF's. From the date that this notice publishes in the **Federal Register**, FDA will no longer accept NFCSF's.

(c) An NFCSF must contain the following:

(1) A completed and signed FDA Form No. 3479; and

(2) Any additional documentation required to establish that each component of the formulation already may be legally marketed for its intended use.

PART 171—FOOD ADDITIVE PETITIONS

8. The authority citation for 21 CFR part 171 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

9. Section 171.1 is amended by revising paragraph (i)(1) to read as follows:

§ 171.1 Petitions.

* * * * *

(i)(1)(i) Within 15 days after receipt, the Food and Drug Administration will notify the petitioner of the acceptance or nonacceptance of a petition, and if not accepted, the reasons therefor. If accepted, the petitioner will be sent a letter stating this and the date of the letter shall become the date of filing for the purposes of section 409(b)(5) of the act. In cases in which the Food and Drug Administration agrees that a premarket notification submitted under section 409(h) of the act may be converted to a petition, the withdrawal date for the premarket notification will be deemed the date of receipt for the FAP.

(ii) If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, the petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified.

(iii) Notwithstanding paragraph (i)(1)(ii) of this section, the petition shall not be filed if the Food and Drug Administration determines that the use identified in the petition should be the subject of a premarket notification under section 409(h) of the act rather than a FAP.

* * * * *

10. Section 171.7 is amended by adding paragraph (c) to read as follows:

§ 171.7 Withdrawal of petition without prejudice.

* * * * *

(c) Any petitioner who has a FAP pending before the agency and who subsequently submits a premarket notification for a use or uses described in such petition, shall be deemed to have withdrawn the petition for such use or uses without prejudice to a future filing on the date the premarket notification is received by FDA.

PART 174—INDIRECT FOOD ADDITIVES: GENERAL

11. The authority citation for 21 CFR part 174 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

12. Section 174.5 is amended by adding paragraph (d)(5) to read as follows:

§ 174.5 General provisions applicable to indirect food additives.

* * * * *

(d) * * *

(5) Food contact substances used in accordance with an effective premarket notification submitted under section 409(h) of the act.

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF FOOD

13. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

14. Section 179.25 is amended by revising paragraph (c) to read as follows:

§ 179.25 General provisions for food irradiation.

* * * * *

(c) Packaging materials subjected to irradiation incidental to the radiation treatment and processing of prepackaged food shall be in compliance with § 179.45, shall be the subject of an exemption for such use under § 170.39 of this chapter, or shall be the subject of an effective premarket notification for such use submitted under § 170.100 of this chapter.

* * * * *

Dated: January 24, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–17653 Filed 7–12–00; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–6730–9]

Hazardous Waste Management Program: Final Authorization of State Hazardous Waste Management Program Revisions for State of Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and request for comment.

SUMMARY: The EPA (also, ''the Agency'' in this preamble) proposes to grant final authorization to the hazardous waste program revisions submitted by the State of Texas for its hazardous waste program revisions, specifically, revisions needed to meet the Resource Conservation and Recovery Act (RCRA) Cluster VI, which contains Federal rules promulgated between July 1, 1995 to June 30, 1996. In the ''Rules and Regulations'' section of this **Federal Register** (FR), EPA is authorizing the State's program revisions as an immediate final rule without prior proposal because the EPA views this action as noncontroversial and anticipates no adverse comments. The Agency has explained the reasons for this authorization in the preamble to the immediate final rule. If the EPA does not receive adverse written comments, the immediate final rule will become effective and the Agency will not take further action on this proposal. If the EPA receives adverse written comments, a second **Federal Register** document will be published before the time the immediate final rule takes effect. The second document may withdraw the immediate final rule or identify the issues raised, respond to the comments and affirm that the immediate final rule will take effect as scheduled. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received on or before August 14, 2000.

ADDRESSES: Mail written comments to Alima Patterson, Region 6, Regional Authorization Coordinator, Grants and Authorization Section (6PD–G), Multimedia Planning and Permitting Division, at the address shown below. You can examine copies of the materials submitted by the State of Texas during normal business hours at the following locations: EPA Region Library, 12th Floor, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–6444; or Texas Natural Resource Conservation Commission, 1700 N. Congress Avenue, Austin TX 78711–3087, (512) 239–6757.

FOR FURTHER INFORMATION CONTACT: Alima Patterson (214) 665–8533.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

Dated: June 14, 2000.

Jerry Clifford,

Acting Regional Administrator, Region 6.

[FR Doc. 00–17489 Filed 7–12–00; 8:45 am]

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