

# **Food Additive Petition Expedited Review - Guidance for Industry and Center for Food Safety and Applied Nutrition Staff**

Written comments may be submitted at any time to the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Such comments will be considered when determining whether to amend the guidance. For questions regarding the use or interpretation of this guidance, contact Robert L. Martin, (202) 418-3074, [RMartin@bangate.fda.gov](mailto:RMartin@bangate.fda.gov)

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Date \_\_\_\_\_**

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# **Food Additive Petition Expedited Review - Guidance for Industry and Center for Food Safety and Applied Nutrition Staff**

## **Purpose**

To describe the criteria and procedures under which expedited review will be conducted for certain food additive petitions that are expected to have a significant impact on food safety.

## **Introduction<sup>1</sup>**

FDA believes it is in the interest of enhanced food safety to review petitions for certain food additive uses in an expedited manner. Expedited review will generally be considered when an additive is intended to decrease the incidence of food-borne illness through its antimicrobial action against human pathogens that might be present in food. For example, FDA has received petitions for the use of sources of radiation and for chemicals such as chlorine dioxide to reduce the levels of pathogenic organisms in various foods.

Designating food additive petitions for expedited review means that the food additive petition would be reviewed ahead of other pending food additive petitions, i.e., the petition will be placed at the beginning of the appropriate review queues.

Petitions under expedited review would be subject to all other controls and requirements applicable to comparable petitions in the standard review process. Accordingly, valid scientific evidence, as defined by Title 21 of the Code of Federal Regulations, section 171.1, would be required to support an expedited review petition. Likewise, the standard for safety and data

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<sup>1</sup>This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

presentation would remain unchanged.

## **Criteria**

In order to provide more rapid approval of food additives that are intended to significantly increase the safety of the food supply, the Office of Premarket Approval (OPA) will consider expedited review of petitions for additives that meet the following criteria:

1. Use of the additive as proposed is intended to significantly decrease human pathogens (e.g., *E. coli.*, *Salmonella*, *Campylobacter*, *Cyclospora*, or *Listeria*) or their toxins in/on food.
2. The petition is complete in terms of 21 CFR 171.1 and appears to contain sufficient data and information to support a decision whether to approve the additive, i.e., the petition satisfies the criteria for filing.

## **Procedures**

1. Identification of Applications for Expedited Review. As food additive petitions are received in the Office of Premarket Approval, the Office Director, in consultation with the Office Management Team (comprised primarily of Division Directors within the Office) will consider these petitions and identify those petitions that meet the criteria for expedited review. Petitioners are encouraged to identify petitions that they believe meet the criteria for expedited review listed above.

2. Determination of Expedited Review. The decision to expedite review will be made at the time a petition is filed. OPA may also designate a petition already under review for expedited review if it determines, during the review, that the petition qualifies for expedited review.

Consumer Safety Officers and review staff should take the opportunity during the post-filing review and decision period of petitions not already undergoing expedited review to determine whether these petitions should be designated for expedited review.

3. Documentation and Processing. After the determination to expedite review has been made, the Consumer Safety Officer assigned to the petition will prepare a written memorandum to the administrative record that identifies, using the criteria outlined above, the reasons for designating the petition for expedited review. OPA will notify the petitioner in writing of the expedited review designation. OPA will also notify the petitioner when any food additive petition is subsequently removed from expedited review designation.

4. Resource Management. It will be the responsibility of the Directors of the reviewing Divisions to ensure that an expedited review petition is reviewed in the most efficient manner, tracked as an expedited review, and completed within established time frames. FDA recognizes that implementation of this policy may affect other review work of OPA because additional resources may be required to review petitions designated for expedited review. All of the following resource issues should be considered as part of the implementation of the expedited review process:

- a. a shift in the workload within the affected reviewing Divisions may be necessary;
- b. scientists from other Divisions or from outside of OPA may be called upon to provide support to those areas in OPA where the standard review queue would otherwise be significantly affected by the needed redistribution of the workload; and
- c. review of the standard (i.e. non-expedited) petitions in reviewing Divisions may occur after the review of petitions designated for expedited review.

5. Review of petition. Except for the position in the review queue, there will be no change in the

procedures for review of petitions designated for expedited review.

5. Monitoring. The Office Management Team and the Office Director of OPA will periodically review, approximately every 90 days, the status of petitions designated for expedited review and will evaluate the effect of the expedited review both on expedited petitions and standard petitions in the review queue to determine whether the allocation of review personnel is appropriate.

6. Public Disclosure. The fact that a petition is being reviewed under these expedited procedures will be publicly disclosed in the form of a list on FDA's World Wide Web (WWW) home page. The list will be maintained on the Center for Food Safety and Applied Nutrition home page, which may be accessed at <http://vm.cfsan.fda.gov>. The list of petitions designated for expedited review will also be provided to appropriate media and FDA information sources so that interested outside parties may determine which petitions have been designated for expedited review.

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