

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 96F-0493]

Gerard T. O'Brien; Denial, Response to Objections

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; order denying objection.

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**SUMMARY:** The Food and Drug Administration (FDA) is denying an objection to the agency's denial of a petition (FAP 7A4530) proposing that the food additive regulations be amended to provide for the safe use of a mixture of hydrogen peroxide and sodium bicarbonate as an antimicrobial agent on fresh poultry. The objector did not request a hearing, and thus waives the right to such a hearing.

**FOR FURTHER INFORMATION CONTACT:** James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3078.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of January 2, 1997 (62 FR 101), FDA announced that a food additive petition (FAP 7A4530) had been filed by Gerard T. O'Brien, 2162 Skyline Dr., Gainesville, GA 30501. The petitioner requested that FDA amend the food additive regulations to provide for the safe use of a mixture of hydrogen peroxide and sodium bicarbonate as an antimicrobial agent on fresh poultry. In the **Federal Register** of September 26, 1997 (62 FR 50617), FDA published an order denying this petition, in accordance with § 171.100(a) (21 CFR 171.100(a)), because FDA concluded that the petition did not contain sufficient data and information to allow the agency to determine either that the food additive is safe for its proposed use or that the additive will have its intended technical effect.

In its denial, the agency explained that the petitioner had failed to provide data and information to demonstrate that the hydrogen peroxide and sodium bicarbonate mixture would significantly reduce pathogenic bacterial contamination on the surface of fresh poultry, e.g., *Salmonella*, *Escherichia coli*, and psychrophiles, and that the petitioner had failed to provide data and information on whether oxidative effects of hydrogen peroxide would occur on poultry as a result of the proposed use. FDA noted that the agency had requested certain data from the petitioner on several occasions during its review of the petition, including laboratory data to demonstrate that there is reduced bacterial contamination on poultry processed with hydrogen peroxide and sodium bicarbonate, TBA (2-thiobarbituric acid) values (an indicator of oxidation) in skin/fat and meat from processed poultry, and a basis to estimate the amount of hydrogen peroxide that reacts with poultry during the proposed treatment. Because the petitioner failed to provide these data and information, FDA did not have a sufficient basis to determine whether the food additive would achieve its intended technical effect or was safe for the intended use. Accordingly, FDA denied the petition.

Under § 171.110 of the food additive regulations, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Section 12.22(a) sets forth the conditions that each objection must meet for filing. Section 12.22(a) provides that each objection must: (1) Be submitted on or before the 30th day after the date of publication of the final rule; (2) be separately numbered; (3) specify with particularity the provision of the order objected to; (4) state whether a hearing is requested; and (5) for each objection for which a hearing is requested, include a detailed description of the factual information to be presented in support of the objection. Failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

In response to the agency's denial of FAP 7A4530, the petitioner, on October 22, 1997, submitted material within the 30-day objection period challenging the denial. The petitioner submitted, as its objection, references to three complaints filed in various legal proceedings in

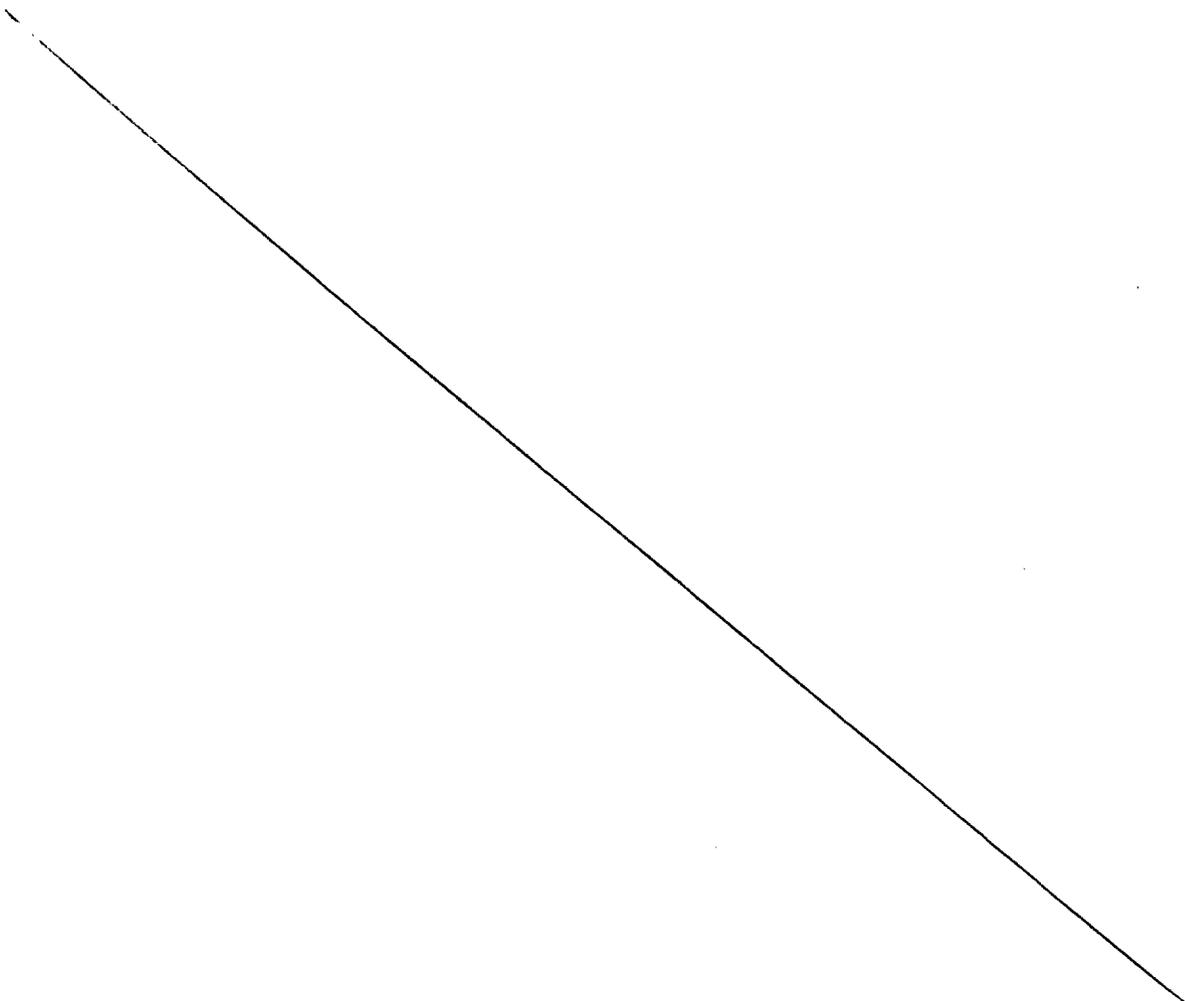
Federal court. Such complaints were filed before the date of the agency's denial of the petition, and therefore, were not written in response to the agency's denial, but were submitted as "objections." A copy of one of the referenced complaints, filed on August 25, 1997, in the U.S. District Court for the Northern District of Georgia, was included in the submission. In addition, the petitioner submitted a copy of the agency's September 26, 1997, order that had been annotated (apparently by the petitioner) with words and statements that asserted that FDA's findings were wrong. The petitioner provided no explanation for its assertions.

FDA has reviewed the material submitted by the petitioner. The submitted material is not in the form that is required for the filing of objections under § 12.22(a). Although the petitioner submitted material that he characterized as "objections," he failed to identify the specific provisions of the agency's order to which he objected. Further, the petitioner did not request a hearing for any "objection" and therefore, waived the right to a hearing under § 12.22(a)(4). Even if the agency assumed that the petitioner, in his submission, made an implicit request for a hearing, the petitioner did not provide a detailed description and analysis of the factual information to be presented in support of each of his objections, as required under § 12.22(a)(5). Therefore, the material submitted did not meet the conditions for filing objections under § 12.22(a).

Moreover, even if the petitioner's submission is assumed to be an objection that meets the requirements of filing and contains an implicit request for a hearing, the petitioner has not met the requirements for the grant of a request for a hearing under § 12.24(b). Specifically, the petitioner has not identified any genuine and substantial issue of fact for resolution at a hearing (§ 12.24(b)(1)). The petitioner has not provided a factual basis for why the data and information that FDA requested, but that were not provided in the petition, are not necessary in order for the agency to determine whether the proposed use of the food additive is safe, or to determine that the proposed use of the additive will achieve its intended technical effect. The petitioner merely asserted that the agency's determination was wrong, but failed to provide a basis for this assertion. Furthermore, because the petitioner did not provide a detailed description and analysis of the

specific factual information intended to be presented in support of any objection, the agency will not use its discretion under § 12.30(b) to order a hearing.

In summary, the petitioner alleges no misapplication of the law by FDA in the agency's order of denial. Moreover, the petitioner has provided the agency with no genuine or substantial issue of fact that could form the basis for FDA to reconsider its decision denying FAP 7A4530. Furthermore, the petitioner's submission provides no basis for granting a hearing because no such request was made, and even if such a request is implied, the petitioner did not include specifically identified reliable evidence that could lead to resolution of any factual issue in dispute. A hearing will not be granted on the basis of mere allegations or denials, or general descriptions of positions



and contentions (§ 12.24(b)(2)). Therefore, in accordance with §§ 12.28 and 12.30(b), FDA is denying in its entirety the petitioner's objection to the agency's order denying FAP 7A4530.

Dated: 8/3/99

August 3, 1999



Margaret M. Dotzel  
Acting Associate Commissioner  
for Policy

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*Michael W. Bell*