Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: December 5, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–33343 Filed 12–31–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0493]

Gerard T. O'Brien; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Gerard T. O'Brien has filed a petition 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.

DATES: Written comments on the petitioner's environmental assessment by February 3, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3078.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7A4530) has been filed by Gerard T. O'Brien, 2162 Skyline Dr., Gainesville, GA 30501. The petition proposes to 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.

FAP 7A4530 was submitted to the agency on September 24, 1987, as FAP 7A4045. On March 9, 1992, because of continued deficiencies in the petition, which the agency had not filed, FDA notified the petitioner that it would not continue its review of this petition. Information concerning microbiological and chemical studies, which the agency had requested in several letters to the petitioner, had not been submitted. These studies were needed to demonstrate the bactericidal effectiveness of the petitioned use of the additive and the dietary exposure to oxidation products that might be formed on the chicken during processing. Therefore, FDA planned no further review.

Since that time, the agency has been corresponding with the petitioner and has still not received the requested information. In a September 18, 1995, letter to FDA the petitioner asked whether he had exhausted his administrative remedies. Before receiving a response from FDA, the petitioner filed a lawsuit against the agency. After the dismissal of this lawsuit, the agency responded to the petitioner's original question in an October 16, 1996, letter saying that the petitioner had not exhausted his administrative remedies and that he could either file a new petition that would include the supplemental information requested by the agency or send a written request to FDA asking the agency to file the petition as submitted in accordance with § 171.1(i)(1) (21 CFR 171.1(i)(1)). The petitioner responded in a November 4, 1996, letter indicating that he wants FDA to approve the proposed use of this additive and does not intend to supplement the petition. Therefore, FDA is filing the petition as submitted, in accordance with § 171.1(i)(1). The agency has assigned a new number (FAP 7A4530) to this petition for administrative purposes.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the original petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before February 3, 1997 submit to the Dockets Management Branch (address above) written comments. 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 office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: December 12, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–33380 Filed 12–31–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0353]

Determination of Regulatory Review Period for Purposes of Patent Extension; DIFFERIN Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DIFFERIN Solution and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product DIFFERIN Solution (adapalene). DIFFERIN Solution is indicated for the topical treatment of acne vulgaris. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DIFFERIN Solution (U.S. Patent No. 5,212,303) from Centre International de Recherches Dermatologiques (CIRD), and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 24, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DIFFERIN Solution represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for DIFFERIN Solution is 2,814 days. Of this time, 1,651 days occurred during the testing phase of the regulatory review period, while 1,163 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: September 18, 1988. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on September 18, 1988.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: March 26, 1993. The applicant claims March 19, 1993, as the date the new drug application (NDA) for DIFFERIN Solution (NDA 20–338) was initially submitted. However, FDA records indicate that NDA 20–338 was submitted on March 26, 1993.

3. *The date the application was approved*: May 31, 1996. FDA has verified the applicant's claim that NDA 20–338 was approved on May 31, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 13 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 3, 1997 submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 1, 1997 for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 20, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–33381 Filed 12–31–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0449]

Current Science and Technology on Fresh Juices; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to February 3, 1997, the comment period on the notice that appeared in the Federal Register of November 27, 1996 (61 FR 60290). The notice announced a meeting to review the current science, including technological and safety factors, relating to fresh juices and to consider any measures necessary to provide safe fruit juices. The agency is taking this action in response to several requests for an extension of the comment period.

DATES: Written comments by February 3, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS–22), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4251, (FAX) 202–205–4970, (Internet) CMD@FDACF.SSW.DHHS.GOV.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 27, 1996 (61 FR 60290), FDA requested information and data on: (1) Appropriate good manufacturing practices (GMP's) in juice processing; (2) identification of critical control points in juice processing under a Hazard Analysis and Critical Control Point System (HACCP); (3) whether pasteurization of fresh juices is appropriate or necessary; (4) sanitizers that are available to control pathogens of concern; (5) alternative available food additives that will ensure safety of fresh juices; (6) any new technologies/intervention strategies that are becoming available that appear to be effective in the control of *E. coli 0157:H7* or other pathogens of concern; and (7) the advice that should be given to consumers on fresh and other juice products. Interested persons were given until January 3, 1997, to submit written comments on the notice.

FDA received several requests for an extension of the comment period. After careful consideration, FDA has decided to extend the comment period to February 3, 1997, to facilitate the submission of relevant information on the above topics.

Interested persons may, on or before February 3, 1997, submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be