a brief, balanced account or analysis of how this literature either supports or fails to support that authoritative statement should be submitted.

The information collection provisions contained in the guidance received emergency approval from OMB under control number 0910–0374. The emergency approval expires on June 30, 1999. FDA is now seeking an extension of the OMB approval.

As part of this process, the agency requested comments on the proposed collection of information in the **Federal Register** of August 13, 1998 (63 FR 43400; corrected at 63 FR 49130, September 14, 1998).

One comment was submitted by a food industry association. This comment addressed several points, only some of which were relevant to the information collection provisions contained in the guidance. Most of the other points were relevant to a group of interim final rules the agency issued in June 1998 in response to a notification for nine claims based on authoritative statements; these points will be addressed in the rulemakings to which they pertain. The points in the comment that are relevant to the information collection provisions in the guidance are discussed in the following paragraphs.

The comment first stated that the guidance goes further than provided by the statute in two respects: First, in the guidance's request that notifications include a ''potentially burdensome'' account or analysis of how the scientific literature relating to the relationship between a nutrient and a disease or health-related condition or to the nutrient level to which the claim refers either supports or fails to support the authoritative statement, and second, in the guidance's request that information on analytical methodology for the nutrient that is the subject of the claim be submitted. The comment expressed the opinion that, although the kind of information identified by the guidelines may be useful to FDA and could be submitted voluntarily, the information should not be a mandatory element of a notification; moreover, the lack of such information should not be the basis for prohibiting a health claim based on an authoritative statement. The comment stated that notifications should not impose any significant regulatory burden on manufacturers, adding that, as a general matter, it would object to any expansion of information required as part of a notification.

First, the agency notes that neither the account of the scientific literature relating to the claim nor the information about analytical methodology is described in the guidance as a mandatory element of a notification. In both cases, the agency uses the term ''should'' to convey its view that the inclusion of such information is desirable. Further, the guidance states explicitly, ''An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. ''

Second, the agency does not believe that providing the account of the relevant scientific information and the analytical methodology are overly burdensome. FDA believes that most companies would prepare an account of the scientific literature that supports or fails to support a claim in the normal course of evaluating potential claims based on authoritative statements and making the business decision of whether to use such claims in the marketing of their products. Similarly, FDA believes that most companies would be knowledgeable about the analytical methodologies that might be used to determine the amount of a nutrient or other substance present in their products. The agency recognizes that including such information in a notification causes some burden. The agency provided an estimate of this burden in the August 13, 1998, notice. This estimate also appears in Table 1 of this document. No comments were submitted addressing the accuracy of this estimate.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Guidance for Notification	12	5	60	1	60

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The agency believes that this guidance will enable food producers to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the act during the interim period while the agency is initiating notice-and-comment rulemaking to implement those sections of the act. FDA intends to review the notifications it receives to ensure that they comply with the criteria established for them by the act.

These estimates are based on FDA's experience with health claims and nutrient content claims and with other similar notification procedures that fall under its jurisdiction. Because the claims are based on authoritative statements of certain scientific bodies of the Federal Government or the National Academy of Sciences or one of its subdivisions, FDA believes that the information submitted with a notification will be either provided as part of the authoritative statement or readily available to firms wishing to make claims.

The hour burden estimates contained in Table 1 of this document are for the information collection requests in the guidance only and do not include statutory requirements specifically mandated by the act.

Dated: April 23, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–10792 Filed 4–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–1074]

Life Technologies, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Life Technologies, Inc. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of quaternary amine cellulose ion exchange resins in the isolation and purification of protein

concentrates and isolates from aqueous process streams for food processing.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

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 9A4659) has been filed by Life Technologies, Inc., 9800 Medical Center Dr., Rockville, MD 20850–3321. The petition proposes to amend the food additive regulations in § 173.25 *Ion-exchange resins* (21 CFR 173.25) to provide for the safe use of quaternary amine cellulose ion exchange resins in the isolation and purification of protein concentrates and isolates from aqueous process streams for food processing.

The agency has determined under 21 CFR 25.32(j) 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.

Dated: April 19, 1999.

Alan M. Rulis,

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

[FR Doc. 99–10918 Filed 4–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 90F–0018]

Rohm and Haas Co.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 0B4189) proposing that the food additive regulations be amended to provide for the expanded use of n-alkylglutarimide/acrylic copolymers as articles or components of articles intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 9, 1990 (55 FR 4690), FDA announced that a food additive petition (FAP 0B4189) had been filed by Rohm and Haas Co., Independence Mall West, Philadelphia, PA 19105 (currently c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). The petition proposed to amend the food additive regulations in § 177.1060 *n-Alkylglutarimide/acrylic copolymers* (21 CFR 177.1060) to provide for the expanded use of *n*-alkylglutarimide/acrylic copolymers as articles or components of articles intended for use in contact with food also under the conditions of use A, B, and C described in Table 2 of 21 CFR 176.170(c). Rohm and Haas Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: April 2, 1999.

Laura M. Tarantino,

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

[FR Doc. 99–10794 Filed 4–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0488]

Determination of Regulatory Review Period for Purposes of Patent Extension; Gonal–F®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Gonal–F® 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 Gonal–F® (follitropin alpha/beta). Gonal–F® is indicated for the induction of ovulation and pregnancy in the anovulatory infertile patient in whom he cause of infertility is functional and not due to primary ovarian failure; and for the development of multiple follicles in the ovulatory patient participating in an Assisted Reproductive Technology (ART) program. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Gonal–F® (U.S. Patent No. 5,156,957) from Genzyme Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 14, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Gonal–F® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office