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

Form No.	CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 2541a (Process Filing)	108.25 (c)(2) and 108.35(c)(2)	1,000	6.5	6,500	.333	2,165
Form FDA 2541c (Process Filing)	108.35(c)(2)	1,000	.50	500	.75	375
Total						2,591

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Part	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
108, 113, and 114	5,865	1	5,865	250	1,466,250

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

The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is insignificant because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. To avoid double counting, estimates for §§ 108.25(g) and 108.35(h) have not been included because they merely cross-reference recordkeeping requirements contained in parts 113 and 114.

Dated: April 23, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–10797 Filed 4–29–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0320]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notification of a Health Claim or a Nutrient Content Claim Based on an Authoritative Statement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by June 1, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Notification of a Health Claim or a Nutrient Content Claim Based on an Authoritative Statement (OMB Control Number 0910–0374—Extension)

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997, provides that a food producer may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of certain scientific bodies of the Federal Government or of the National Academy of Sciences or any of its subdivisions. Under these sections of the act, a food producer may use such a claim in the labeling of an appropriate product 120 days after a complete notification of the claim is submitted to FDA.

In the **Federal Register** of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' (hereinafter referred to as ''the guidance''). As stated in that guidance, under section 403(r)(2)(G) and (r)(3)(C) of the act, a notification is to include: (1) The exact words used in the claim, (2) a concise description of the basis upon which the submitter relied for determining that the requirements for an authoritative statement have been satisfied, (3) a copy of the statement upon which the submitter relied in making the claim, and (4) for a health claim, a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers, or, for a nutrient content claim, a balanced representation of the scientific literature relating to the nutrient level to which the claim refers.

The guidance provides the agency's interpretation of terms central to the submission of a notification and the agency's views on the information that should be included in such a notification. In addition to the information specifically required by the act to be such a notification, the guidance states that a notification should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. Further, the guidance explains that to present a balanced representation of the scientific literature, as required by statute, a bibliography of the scientific literature on the topic of the claim should be compiled. The guidance also states that

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.

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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