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
310.305(c)(5)	1	1	1	1	1
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	683	15	10,245	5	286,860
Total					286,866

[1] The reporting burden for §§ 310.305(c)(1), (c)(2), and (c)(3), and 314.80(c)(1)(i) and (c)(1)(ii)(c) was reported under OMB Control No. 0910–0291. 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 Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
310.305(f)	25	1	25	1	25
314.80(i)	683	1	683	1	683
Total					708

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

Dated: February 12, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–4456 Filed 2–22–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 81F–0387]

Abbott Laboratories; 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 2B3593), filed by Abbott Laboratories, proposing that the food additive regulations be amended to provide for the safe use of cyclohexylsulfamic acid as a catalyst in resinous and polymeric coatings.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 19, 1982 (47 FR 2791), FDA announced that a food additive petition (FAP 2B3593) had been filed by Abbott Laboratories, North Chicago, IL 60064 (now 100 Abbott Park Rd., Abbott Park, IL 60064–6091). The petition proposed to amend the food additive regulations to provide for the safe use of cyclohexylsulfamic acid as a catalyst in resinous and polymeric coatings. Abbott Laboratories has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: January 29, 2002.

Leslye M. Fraser,

Acting Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 02–4381 Filed 2–22–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–1221]

Determination of Regulatory Review Period for Purposes of Patent Extension; Celexa

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Celexa 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 that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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