ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
312.7	7	1	7	24 hours	168
312.10	12	1	12	5 hours	60
312.23	1,623	1	1,623	100 hours	162,300
312.30	1,201	9	10,809	84 hours	907,956
312.31	880	5.64	4,963	8 hours	39,704
312.32	440	8	3,520	20 hours	70,400
312.33	1,517	2.6	3,944	450 hours	1,774,800
312.35	5	1	5	260 hours	1,300
312.36	300	1	300	5 hours	1,500
312.38	579	1.2	695	45 minutes	521
312.44	300	1	300	16 hours	4,800
312.45	205	1.4	287	5 hours	1,435
312.47	100	1	100	24 hours	2,400
312.53	4,000	1	4,000	84 hours	336,000
312.55	500	1	500	16 hours	8,000
312.56	560	2.4	1,344	84 hours	112,896
312.58	260	2.6	676	84 hours	56,784
312.64	1,500	1.3	2,000	24 hours	48,000
312.66	700	1	700	8 hours	5,600
312.83	5	1	5	160 hours	800
312.85	260	2.6	676	960 hours	648,960
312.110	30	11.6	348	24 hours	8,352
312.120(b)	560	2.4	1,344	100 hours	134,000
312.120(c)(3)	560	2.4	1,344	3 hours	4,032

There are no capital costs or operating and maintenance costs associated with this information collection.

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
312.52	280	1	280	30 minutes	140
312.57	560	2.4	1,344	100 hours	134,400
312.59	250	2.4	600	8 hours	4,800
312.62(a)	4,000	1	4,000	40 hours	160,000
312.62(b)	4,000	10	40,000	40 hours	1,600,000
312.160(a)	250	40	10,000	30 minutes	5,000
312.160(c)	250	30	7,500	30 minutes	3,750
Total Burden Hours					6,238,858

There are no capital costs or operating and maintenance costs associated with this information collection.

Dated: October 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy.

[FR Doc. 96–27993 Filed 10–30–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0401]

BASF Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BASF Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyamide-ethyleneimine-epichlorohydrin resin as a retention aid in the production of paper and paperboard intended for use in contact with dry food.

DATES: Written comments on the petitioner's environmental assessment by December 2, 1996.

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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 6B4501) has been filed by BASF Corp., 11501 Steele Creek Rd., Charlotte, NC 28273. The petition proposes to amend the food additive regulations in § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) to provide for the safe use of polyamide-ethyleneimine-epichlorohydrin resin for use as a retention aid in the production of paper and paperboard intended for use in contact with dry food.

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 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 December 2, 1996 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: October 16, 1996.

Alan M. Rulis,

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

[FR Doc. 96–27994 Filed 10–30–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0344]

Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use.'' This guidance document was prepared by the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). On May 14, 1996, FDA published a final rule that amended the biologics regulations to eliminate the establishment license application (ELA) for manufacturers of certain products. Instead, a sponsor may submit a biologics license application that includes a chemistry, manufacturing, and controls (CMC) section. This guidance document is intended to assist applicants in the preparation of the CMC information for marketing applications for certain specified products, including therapeutic recombinant deoxyribonucleic acid (DNA)-derived products or monoclonal antibody products for in vivo use, as well as those recombinant DNA-derived products regulated using a new drug application submitted to CDER.

DATES: Written comments may be submitted at any time, however, to ensure comments are considered for the next revision they should be submitted by January 29, 1997.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or Monoclonal Antibody Product for In Vivo Use'' to the Manufacturers Assistance and Communications Staff (HFM–42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail or fax by calling the CBER Fax Information System at 1–888–223–7329.

Persons with access to Internet may obtain the document in several ways. Users of ''Web Browser'' software, such as Mosaic, Netscape, or Microsoft Internet Explorer may obtain this document via the World Wide Web by using the following Uniform Resource Locators (URL's):

http://www.fda.gov/cber/cberftp.html
ftp://ftp.fda.gov/CBER/

The document may also be obtained via File Transfer Protocol (FTP). Requestors should connect to the FDA FTP Server, FTP.FDA.GOV (192.73.61.21.). The CBER documents are maintained in a subdirectory called ''CBER'' on the server. Logins with the user name of anonymous are permitted, and the user's e-mail address should be sent as the password. The ''READ.ME'' file in that subdirectory describes the available documents which may be available as an ASCII text file (*.TXT), or a Word Perfect 5.1 or 6.x document (*.w51,wp6), or both. Finally, the document can be obtained by ''bounce-back e-mail.'' A message should be sent to: ''CMCDNAMCA@al.cber.fda.gov''.

Submit written comments on the guidance to the Dockets Managements Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: As outlined in the President's November, 1995, National Performance Review, ''Reinventing the Regulation of Drugs Made from Biotechnology,'' FDA has announced that it will develop a single harmonized application form for all licensed biological products and all drug products. In the Federal Register of May 14, 1996 (61 FR 24227), FDA published a final rule entitled ''Elimination of the Establishment License Application for Specified Biotechnology and Specified Synthetic Biological Products.'' The final rule, also part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives, amended the biologics regulations to eliminate ELA for specified biotechnology and specified synthetic biological products, including: Therapeutic DNA plasmid products, therapeutic synthetic peptide products of 40 or fewer amino acids, monoclonal antibody products for in vivo use, and therapeutic recombinant DNA-derived products.

Prior to the publication of the final rule, the manufacturers of these biological products were required to submit both a product license application and an ELA to FDA for marketing approval (21 CFR 601.2). Under the final rule, a company may submit information in a single biologics license application for specified biotechnology and specified synthetic biological products to harmonize the approval requirements for specified biotechnology and specified synthetic biological products with similar drug products approved under the new drug provisions of the Federal Food, Drug, and Cosmetic Act (the act).

The guidance document announced in this notice is intended to provide assistance to applicants in preparing the CMC section of the harmonized application for a therapeutic