SUPPLEMENTARY INFORMATION: On August 21, 1996, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was signed into law (Pub. L. 104–191). Section 421 of HIPAA makes changes, described below, to three areas in the continuation coverage rules applicable to group health plans under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), as amended. These three areas relate to the disability extension, the definition of qualified beneficiary and the duration of COBRA continuation coverage. These changes are effective beginning January 1, 1997, regardless of when the event occurs that entitles an individual to COBRA continuation coverage.

Section 421(e) of HIPAA requires group health plans that are subject to COBRA to notify, by November 1, 1996, individuals who have elected COBRA continuation coverage of these changes. The Department is issuing this notice to apprise State and local government employers and plan administrators of the changes in the continuation coverage rules made by HIPAA and to inform them of their obligation under HIPAA to notify qualified beneficiaries of such changes. Such notification must be given by November 1, 1996, to each qualified beneficiary who has elected continuation coverage. The following is a discussion of the specific changes in the continuation coverage rules made by HIPAA.

Disability Extension

Under current law, if an individual is entitled to COBRA continuation coverage because of a termination of employment or reduction in hours of employment, the plan generally is only required to make COBRA continuation coverage available to that individual for 18 months. However, if the individual entitled to the COBRA continuation coverage is disabled (as determined under the Social Security Act) and satisfies the applicable notice requirements, the plan must provide COBRA continuation coverage for 29 months, rather than 18 months. Under current law, the individual must be disabled at the time of the termination of employment or reduction in hours of employment. HIPAA makes changes to the current law to provide that, beginning January 1, 1997, the disability extension will also apply if the individual becomes disabled at any time during the first 60 days of COBRA continuation coverage. HIPAA also makes it clear that, if the individual entitled to the disability extension has non-disabled family members who are entitled to COBRA continuation coverage, those non-disabled family members are also entitled to the 29 month extended period of coverage.

Definition of Qualified Beneficiary

Individuals entitled to COBRA continuation coverage are called qualified beneficiaries. Individuals who may be qualified beneficiaries are the spouse and dependent children of a covered employee and, in certain cases, the covered employee. Under current law, in order to be a qualified beneficiary an individual must generally be covered under a group health plan on the day before the event that causes a loss of coverage (such as a termination of employment, or a divorce from or death of the covered employee). HIPAA changes this requirement so that a child who is born to the covered employee, or who is placed for adoption with the covered employee, during a period of COBRA continuation coverage is also a qualified beneficiary.

Duration of COBRA Coverage

Under the COBRA rules there are situations in which a group health plan may stop making continuation coverage available earlier than usually permitted. One of those situations is where the qualified beneficiary obtains coverage under another group health plan. Under current law, if the other group health plan limits or excludes coverage for any preexisting condition of the qualified beneficiary, the plan providing the COBRA continuation coverage cannot stop making the COBRA continuation coverage available merely because of the coverage under the other group health plan. HIPAA makes a coordinating change to the COBRA rules so that if a group health plan limits or excludes benefits for preexisting conditions but because of the new HIPAA rules those limits or exclusions would not apply to (or would be satisfied by) an individual receiving COBRA continuation coverage, then the plan providing the COBRA continuation coverage can stop making the COBRA continuation coverage available. The HIPAA rules limiting the applicability of exclusions for preexisting conditions become effective in plan years beginning on or after July 1, 1997 (or later for certain plans maintained pursuant to one or more collective bargaining agreements).

Notice to Employees

As indicated above, group health plans maintained by State and local government employers subject to Title XXII of the PHS Act are required to notify their qualified beneficiaries who have elected continuation coverage of the amendments described above. This notice is required to be given by November 1, 1996. This Department believes that supplying qualified beneficiaries with the information set forth above (or with a copy of this notice) would constitute compliance with the notice requirement of section 421(e) of HIPAA if this information is sent to each qualified beneficiary who has elected continuation coverage by first class mail at the last known address of the qualified beneficiary by November 12, 1996.

This Department published a notice in the Federal Register on January 7, 1987, setting forth guidance on the Title XXII requirements. 52 FR 604–606. Included as an appendix to that notice was a model statement that covered employers (or the group health plans they maintain) could provide their employees about their continuation coverage rights. We also urge these employers to modify the general notice regarding continuation coverage rights to make it consistent with the HIPAA amendments. As provided in section 2206 of the PHS Act, the group health plan maintained by these employers must provide such notice to their employees at the time of commencement of coverage under the plan; in addition, the employer, the employee, and the plan administrator have certain other notice requirements related to specific qualifying events.

Dated: October 25, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–27964 Filed 10–29–96; 8:45 am]

BILLING CODE 4150–04–M

Food and Drug Administration

[Docket No. 96N–0287]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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.

DATES: Submit written comments on the collection of information by December 2, 1996.

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, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Investigational New Drug Application (IND) Regulations (21 CFR Part 312) (OMB Control Number 0910–0014)

FDA has the responsibility under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) to issue regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs can be conducted. The IND information requirements are needed to ensure the safe and ethical investigation of the safety and effectiveness of new drugs.

FDA is charged with implementing statutory requirements that drug products marketed in the United States be shown to be safe and effective and be properly manufactured and properly labeled for their intended uses. The act provides in section 505(a) that a new drug may not be introduced or delivered for introduction into interstate commerce in the United States unless FDA has previously approved a new drug application (NDA). FDA approves an NDA only if the sponsor of the application first demonstrates that the drug is safe and effective for the conditions prescribed, recommended, or suggested in the product's labeling. Proof must consist, in part, of adequate and well-controlled studies, including studies in humans, that are conducted by qualified experts.

The IND regulations establish reporting requirements that include an initial application as well as amendments to that application, reports on significant revisions of clinical investigation plans, and information on a drug's safety or effectiveness. In addition, the sponsor is required to give FDA an annual summary of the previous year's clinical experience. Submissions are reviewed by medical officers and other agency scientific reviewers assigned responsibility for overseeing the specific study.

The IND regulations also contain recordkeeping requirements that pertain to the responsibilities of sponsors and investigators. The detail and complexity of these requirements is dictated by the scientific procedures and human subject safeguards which must be followed in the clinical tests of investigational new drugs.

FDA estimates the burden of the information collection provisions of the IND regulations as follows:

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