

Dated: December 7, 1995.

Clifton R. Gaus, Sc.D.,
Administrator.

[FR Doc. 95-30478 Filed 12-13-95; 8:45 am]
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Food and Drug Administration

[Docket No. 95G-0389]

Aplin & Barrett Ltd.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Aplin & Barrett Ltd., has filed a petition (GRASP 5G0417) proposing to affirm that nisin preparation is generally recognized as safe (GRAS) as an antimicrobial agent in sauces and nonstandardized salad dressings.

DATES: Written comments by February 27, 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:

Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3072.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Aplin & Barrett Ltd., c/o 700 13th St. NW., suite 1200, Washington, DC 20005, has filed a petition (GRASP 5G0417) proposing that nisin preparation be affirmed as GRAS for use as an antimicrobial agent in sauces and nonstandardized salad dressings.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 (21 CFR 170.30) and 170.35 is filed by the agency. There is no prefilig review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If 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).

Interested persons may, on or before February 27, 1996, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 21, 1995.

Alan M. Rulis,
Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.
[FR Doc. 95-30500 Filed 12-13-95; 8:45 am]
BILLING CODE 4160-01-F

Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection

techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection

Request: Revision of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice (Formerly: Remittance Advice Report) and Prior Quarter Adjustment Statement; *Form No.:* HCFA-304, HCFA-304a; *Use:* The Omnibus Budget Reconciliation Act of 1990 requires drug labelers to enter into and have in effect a rebate agreement with HCFA for States to receive funding for drugs dispensed to Medicaid recipients.

The regulation at 42 CFR 447.534 requires labelers to report specific drug rebate data to States when payment is made; *Affected Public:* Business or other for profit; *Number of Respondents:* 520; *Total Annual Responses:* 2,080; *Total Annual Hours Requested:* 170,560. To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collection should be sent within 60 days of this notice direct to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Linda Mansfield, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 7, 1995.

Kathleen B. Larson,
Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.
[FR Doc. 95-30475 Filed 12-13-95; 8:45 am]
BILLING CODE 4120-03-P

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any