

Governors not later than August 15, 1995.

A. Federal Reserve Bank of Chicago
(James A. Bluemle, Vice President) 230
South LaSalle Street, Chicago, Illinois
60690:

1. *Ida Grove Bancshares, Inc.*, Ida
Grove, Iowa; to engage *de novo* in
making and servicing loans, pursuant to
§ 225.25(b)(1) of the Board's Regulation
Y.

Board of Governors of the Federal Reserve
System, July 25, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95-18694 Filed 7-28-95; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

White House Conference on Aging

AGENCY: White House Conference on
Aging, AoA, HHS.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given,
pursuant to Title II of the Older
Americans Act Amendments of 1987,
Pub. L. 100-175 as amended by Pub. L.
102-375 and Pub. L. 103-171, that the
1995 White House Conference on Aging
Advisory Committee on Disabilities will
hold a meeting on Thursday, August 10,
1995 from 10 a.m. to 2:30 p.m. More
specific information on the location of
the meeting can be obtained by calling
the telephone number given below.

The meeting of the Committee shall
be open to the public. Records shall be
kept of all Committee proceedings and
will be available for public inspection at
501 School Street, SW, 8th Floor,
Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT:
White House Conference on Aging, 501
School Street, SW, 8th Floor,
Washington, DC 20024; telephone (202)
245-7116.

Dated: July 25, 1995.

Fernando M. Torres-Gil,

Assistant Secretary for Aging.

[FR Doc. 95-18701 Filed 7-28-95; 8:45 am]

BILLING CODE 4130-02-M

Food and Drug Administration

[Docket No. 95F-0191]

General Electric Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing
that the General Electric Co. has filed a
petition proposing that the food additive
regulations be amended to provide for
the safe use of polyestercarbonate resins
produced by the condensation of 4,4'-
isopropylidenediphenol, carbonyl
chloride, terephthaloyl chloride, and
isophthaloyl chloride such that the
finished resins are composed of 45 to 85
percent ester of which up to 55 percent
is the terephthaloyl isomer, as articles or
components of articles in contact with
food.

DATES: Written comments on the
petitioner's environmental assessment
by August 30, 1995.

ADDRESSES: Submit written comments
to the Dockets Management Branch
(HFA-305), Food and Drug
Administration, rm. 1-23, 12420
Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Richard H. White, Center for Food
Safety and Applied Nutrition (HFS-
216), Food and Drug Administration,
200 C St. SW., Washington, DC 20204,
202-418-3094.

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 5B4470) has been filed by
the General Electric Co., One Lexan
Lane, Mt. Vernon, IN 47620-9364. The
petition proposes to amend the food
additive regulations in § 177.1585
Polyestercarbonate resins (21 CFR
177.1585) to provide for the safe use of
polyestercarbonate resins produced by
the condensation of 4,4'-
isopropylidenediphenol, carbonyl
chloride, terephthaloyl chloride, and
isophthaloyl chloride such that the
finished resins are composed of 45 to 85
percent ester of which up to 55 percent
is the terephthaloyl isomer, as articles or
components of articles in contact with
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 August 30,
1995, 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: July 14, 1995.

George W. Pauli,

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

[FR Doc. 95-18626 Filed 7-28-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95E-0093]

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

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) has determined
the regulatory review period for
NISOCOR 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
which claims that human drug product.
ADDRESSES: Written comments and
petitions should be directed to the
Dockets Management Branch (HFA-
305), Food and Drug Administration,
rm. 1-23, 12420 Parklawn Dr.,
Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Brian J. Malkin, Office of Health Affairs
(HFY-20), Food and Drug
Administration, 5600 Fishers Lane,
Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug
Price Competition and Patent Term
Restoration Act of 1984 (Pub. L. 98-417)
and the Generic Animal Drug and Patent
Term Restoration Act (Pub. L. 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 have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product NISOCOR (nisoldipine). NISOCOR is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NISOCOR (U.S. Patent No. 4,154,839) from Bayer AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 22, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NISOCOR represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for NISOCOR is 4,965 days. Of this time, 4,292 days occurred during the testing phase of the regulatory review period, while 673 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i))*

became effective: July 2, 1981. The applicant claims May 22, 1989, as the date the investigational new drug application (IND) became effective, based on IND 33,244. However, FDA records indicate that the effective date for the first IND submitted for NISOCOR, IND 18,813, was July 2, 1981, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* April 1, 1993. The applicant claims March 31, 1993, as the date the new drug application (NDA) for NISOCOR (NDA 20-356) was initially submitted. However, FDA records indicate that NDA 20-356 was submitted on April 1, 1993.

3. *The date the application was approved:* February 2, 1995. FDA has verified the applicant's claim that NDA 20-356 was approved on February 2, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,377 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 29, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 29, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 19, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95-18687 Filed 7-28-95; 8:45 am]

BILLING CODE 4160-01-F

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda Purpose: To review and evaluate grant applications

Committee Name: National Institute of Mental Health Special Emphasis Panel

Date: July 30-August 1, 1995

Time: 7 p.m.

Place: Galleria Park Hotel, 191 Sutter Street, San Francisco, CA 94104

Contact Person: Jean G. Noronha, Parklawn Building, Room 9C-18, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301, 443-1000.

Committee Name: National Institute of Mental Health Special Emphasis Panel

Date: August 2-August 4, 1995

Time: 7 p.m.

Place: Madison Hotel, 1177 15th Street NW., Washington, DC 20036

Contact Person: Phyllis D. Artis, Parklawn Building, Room 9C-26, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301, 443-6470.

Committee Name: National Institute of Mental Health Special Emphasis Panel

Date: August 16, 1995

Time: 8:30 a.m.

Place: Loews, 51st and Lexington, New York, NY

Contact Person: Angela L. Redlingshafer, Parklawn Building, Room 9C-18, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301, 443-1367.

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meetings due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, Small Business Innovation Research; 93.242, Mental Health