and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, http://www.fda.gov/cber/guidelines.htm, FAX 1–888–CBERFAX or 301–827–3844, Mail: the Voice Information System at 800–835–4709 or 301–827–1800; or Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), 7500 Standish Pl., Rockville, MD 20855, 301–594–1755, http://www.fda.gov/cvm.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Nancy M. Ostrove, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828, or via e-mail at ''ostrove@cder.fda.gov''.

Regarding prescription human biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via e-mail at ''stifano@cber.fda.gov''.

Regarding prescription animal drugs: Mukund R. Parkhie, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6642, or via e-mail at ''mparkhie@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 12, 1997 (62 FR 43171), FDA announced the availability of a draft guidance for industry concerning consumer-directed broadcast advertisements. The draft guidance was intended to describe how advertisers could fulfill their obligations under the regulations to provide consumers with necessary risk information in connection with prescription drug advertisements broadcast through general public media such as radio, television, and telephone communications systems. The prescription drug advertising regulations (§ 202.1 (21 CFR 202.1)) distinguish between print and broadcast advertisements. Print advertisements must include a ''brief summary,'' which generally contains each risk concept in the product's approved package labeling. In contrast, advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the presentation; this is sometimes called the ''major statement.'' Sponsors of broadcast advertisements are also required to present a brief summary, or alternatively, may make ''adequate provision * * * for dissemination of the approved or permitted package labeling in connection with the broadcast presentation'' (§ 202.1(e)(1)). The draft guidance described and explained the rationale behind one possible multifaceted approach that would fulfill the ''adequate provision'' requirement.

After considering comments received by the public, FDA has revised the draft guidance and is publishing it as a final guidance. FDA notes that although the comments did not address the specific issue of telephone advertisements, the lack of a specific discussion concerning such advertisements may have led to the assumption that the same multifaceted approach appropriate for television and radio advertisements was also appropriate for telephone advertisements. Therefore, in the final guidance FDA clarified its position with regard to fulfilling the ''adequate provision'' requirement for telephone advertisements. Aside from the addition of this clarification and the revision of introductory language to reinforce the importance in broadcast advertisements of complying with the more general requirements of the advertising regulations, there were no major revisions to the draft guidance.

As specified in its good guidance practices policy (62 FR 8961, February 27, 1997), the agency is not obliged to specifically address every comment on a draft or final guidance. However, because this draft guidance had a substantial impact on the direct-to-consumer broadcast environment, FDA believes that discussion of the agency's response to some of the issues raised in the comments will be helpful to certain individuals and groups. Therefore, FDA has placed a document entitled ''Consumer-Directed Broadcast Advertisements Guidance: Questions and Answers'' in the docket with this final guidance (see docket number in brackets in the heading of this document), as well as on FDA's website at ''www.fda.gov/cder/guidance/index.htm''.

As discussed in the August 12, 1997, **Federal Register** notice announcing availability of the draft guidance, within 2 years of publication of this final guidance, FDA intends to evaluate its effects on the public health. At the end of this evaluation period, FDA will determine whether this guidance should be withdrawn, continued, or modified to reflect the agency's current thinking.

This guidance for industry represents the agency's current thinking on consumer-directed broadcast advertisements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the final guidance to the Dockets Management Branch (address above). 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. The final 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.

Dated: June 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–20364 Filed 8–6–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1055–NC]

Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces additional applications that we have received from hospitals requesting waivers from entering into agreements with their designated organ procurement organizations. Section 1138(a)(2) of the Social Security Act allows the Secretary of the Department of Health and Human Services to grant waivers to hospitals that want to enter into an agreement with a specific OPO that is not the designated OPO for the hospital's service area. This notice requests comments from OPOs and the general public for our consideration in determining whether these waivers should be granted.

COMMENT DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 8, 1999.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health

and Human Services, Attention: HCFA–1055–NC, P.O. Box 9016, Baltimore, MD 21244–9016.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1055–NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, Monday through Friday from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Mark A. Horney, (410) 786–4554.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1138(a)(1)(A)(iii) of the Social Security Act (the Act) provides that a participating hospital must notify its designated organ procurement organization (OPO) of potential organ donors. The designated OPO, as defined under section 1138(a)(3)(B) of the Act, is determined by the service area in which the hospital is located. Under section 1138(a)(1)(C) of the Act, the hospital must have an agreement with only that designated OPO to identify potential organ donors.

Section 1138(a)(2) of the Act provides that a participating hospital may obtain a waiver of these requirements from the Secretary of the Department of Health and Human Services (the Secretary). A waiver allows the hospital to have an agreement with an OPO other than the designated OPO if the conditions specified in section 1138(a)(2)(A) of the Act are met.

Section 1138(a)(2)(A) states that in granting a waiver, the Secretary must determine that the waiver: (1) Is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver.

In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO service area due to the changes made on or after December 28, 1992, in definition of metropolitan statistical areas (MSAs); and (4) the length and continuity of a hospital's relationship with the OPO other than the designated OPO.

Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application within 30 days of receiving the application and offer interested parties an opportunity to comment in writing within 60 days of the published notice.

The regulations at 42 CFR 486.316(d) provide that if we change the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver within 30 days of notice of the change in designation. The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under section 1138(a)(2)(A) of the Act and have been incorporated into the regulations at § 486.316(e). Section 486.316(g) further specifies that a hospital may continue to operate under its existing agreement with an out-of-area OPO while we process its waiver request it submitted in accordance with § 486.316(d).

This notice supplements previous notices announcing OPO waivers published in the **Federal Register** on January 19, 1996 (61 FR 1389), May 17, 1996 (61 FR 24941), November 8, 1996 (61 FR 57876), April 21, 1997 (62 FR 19326), September 17, 1997 (62 FR 48872), September 23, 1998 (63 FR 50919), and January 12, 1999 (64 FR 1811).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) that was supplied to each hospital. This Program Memorandum detailed the waiver process and discussed the information that hospitals must provide in requesting a waiver. We indicated that upon receipt of the waiver requests, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

We will review the requests and comments received. During the review process, we may consult, on an as-needed basis, with the Health Resources and Services Administration's Division of Transplantation; the Organ Procurement and Transplantation Network Contractor, United Network for Organ Sharing; and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver requests and notify the affected hospitals and OPOs.

III. Hospital Waiver Requests

As allowed under § 486.316(e), each of the following hospitals has requested a waiver to have an agreement with an alternative, out-of-area OPO. The listing includes the name of the facility, the city and state of the facility, the currently designated area OPO and the requested OPO.

Name of facility	City	State	Designated OPO	Requested OPO
Keweenaw Memorial Hospital	Laurium	MI	WIWU	MIOP
Jefferson Memorial Hospital	Ranson	WV	DCTC	VAOP
Dickinson County Healthcare System	Iron Mountain	MI	WIWU	MIOP

The following two hospitals have requested a waiver under § 486.316 (e) for a reason unrelated to a change in the designated service area of an OPO. These waivers will only be effective upon completion of our review if the provider meets the requirement of § 486.316 (e).

Name of facility	City	State	Designated OPO	Requested OPO
Fairview Hospital	Great Barrington	MA	MAOB	NYAP
Elko General Hospital	Elko	NV	NVLV	UTOP

IV. Key to the OPO Codes

The key to the acronyms used in the listings to identify OPOs and their addresses are as follows:

DCTC—WASHINGTON REGIONAL TRANSPLANT CONSORTIUM, 8110 Gatehouse Road, Suite 101 W, Falls Church, VA 22042
MAOB—NEW ENGLAND ORGAN BANK, One Gateway Center, Newton, MA 02458
MIOP—ORGAN PROCUREMENT AGENCY OF MICHIGAN, 2203 Platt Road, Ann Arbor, MI 48104
NVLV—NEVADA DONOR NETWORK, 4850 Southeastern Avenue, Suite 33, Las Vegas, NV 89119
NYAP—CENTER FOR DONATION AND TRANSPLANT, 218 Great Oaks Blvd., Albany, NY 12203
UTOP—INTERMOUNTAIN ORGAN PROCUREMENT AGENCY, 230 South 500 East, Suite 290, Salt Lake City, UT 84102
VAOP—VIRGINIA ORGAN PROCUREMENT AGENCY, 1527 Houguenot Road, Midlothian, VA 23113
WIWU—UNIVERSITY OF WISCONSIN OPO, University of Wisconsin Hospitals and Clinics, 600 Highland Avenue, Madison, Wisconsin 53792

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on the following issue for the information collection requirements described below.

Designation of one OPO for each service area:

Section 486.316(e) states the requirements for a Medicare or Medicaid participating hospital to qualify for a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. The burden associated with these requirements is currently approved under OMB 0938–0688, HCFA–R–13, Conditions of Coverage for Organ Procurement Organizations, with an expiration date of November 30, 1999.

If you comment on any of these information collection and recordkeeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Groups, Division of HCFA Enterprise Standards, Attention: Louis Blank, HCFA–1055–NC, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Allison Eydt, HCFA Desk Officer, Room 10235, New Executive Office Building, Washington, DC 20503.

Authority: Section 1138 of the Social Security Act (42 U.S.C. 1320b–8).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774 Medicare—Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: August 2, 1999.

Robert A. Berenson,

Director, Center for Health Plans and Providers, Health Care Financing Administration.

[FR Doc. 99–20403 Filed 8–6–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing: ''Novel Method and Composition to Induce Apoptosis in Tumor Cells''

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting J. R. Dixon, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7056 ext 206; fax 301/402–0220; E-Mail: jd212g@NIH.GOV). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION: Invention Title: ''Apoptosis Inducing Agents and Methods'' Inventors: Drs. Lucio Miele (U.S.F.D.A.) and Leslie L. Shelly (NICHD) USPA SN: 60/102,816 [=DHHS Ref. No. E–176–98/0]—Filed with the U.S.P.T.O. October 2, 1998.

Apoptosis or programmed cell death is caused by many anti-tumor drugs and by radiation therapy. These treatment modalities cause apoptosis in tumor cells and in many normal cells in the body. As cancer cells progress towards more aggressive forms, they often become highly resistant to drug- or radiation-induced apoptosis, generally through the loss of function p53, a gene which can trigger apoptosis in response to DNA damage. Thus, novel strategies to induce apoptosis in tumor cells, especially p53-deficient cells, is an attractive and an active area of research.

An antisense molecule is a DNA or RNA which has the opposite beginning to end orientation compared to the ''normal'' gene. These molecules reduce the expression of the target gene by forming pairs with its ''normal'' DNA and RNA. Notch-1 is a gene which is known to be important in controlling cell differentiation in many organisms. Notch-1 is expressed at high levels in several human tumors. However, its function in tumor cells has not been characterized. So far, its role in maintaining tumor cell survival has not been identified. Using a model constituted by a p53-deficient mouse leukemia cell line, NIH scientists found that: 1.) Antisense synthetic DNA oligonucleotides and stable incorporation of an antisense gene (a model for gene therapy) targeting notch-1, when given together with a differentiation-inducing antitumor drug, cause the cells to respond by massive apoptosis rather than differentiation; 2.) stable incorporation of an antisense notch-1 gene increases apoptosis in these cells even in the absence of any antitumor drugs. This suggests that antisense notch-1 treatment, by antisense oligonucleotides or by gene therapy, may be used alone or together with anti-cancer drugs to cause apoptosis in tumor cells.