

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0094]

Draft Guidance for Industry on IND Exemptions for Studies of Lawfully Marketed Cancer Drug or Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "IND Exemptions for Studies of Lawfully Marketed Cancer Drug or Biological Products." This guidance clarifies FDA's policy on exemption from investigational new drug (IND) application requirements for studies of marketed cancer drug or biological products. This guidance is intended to decrease the burden to investigators and regulators of submitting unnecessary IND applications.

DATES: Submit written or electronic comments on the draft guidance by June 10, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, <http://www.fda.gov/cder/guidance/index.htm>, or the Office of Communication, Training, 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>. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by calling the Fax Information System at 1-888-CBER-FAX or 301-827-3844. Submit written or electronic comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Grant A. Williams, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5740, or Patricia Keegan, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5093.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "IND Exemptions for Studies of Lawfully Marketed Cancer Drug or Biological Drug Products." Exemption of certain studies of marketed drugs from IND regulation is allowed under 21 CFR 312.2(b)(1). Investigations that involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product are not exempt. This guidance discusses the risk/benefit determination in the practice of oncology, the pertinent regulations relating to exemption of INDs, FDA's policy for determining exemption status, and specific examples of studies generally considered exempt.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on IND exemptions for studies of lawfully marketed cancer drug or biological products. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. 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 draft 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>

or <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-8462 Filed 4-8-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2002 Competitive Application Cycle for the Nursing Education Loan Repayment Program 93.908

AGENCY: Health Resources and Services Administration.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for the Nursing Education Loan Repayment Program (NELRP) for Fiscal Year 2002.

Authorizing Legislation: These applications are solicited under section 846 of the Public Health Service (PHS) Act, as amended, which authorizes loan repayment, in the amount of 30 percent of the outstanding principal and interest on nursing education loans for each of the first two years of full-time nursing service completed in an eligible health facility, and 25 percent for a third year of service completed.

Eligible Applicants: An individual is eligible to apply for NELRP if the individual: (1) Has received a baccalaureate or associate degree in nursing, a diploma in nursing, or a graduate degree in nursing; (2) has obtained one or more nursing student loans authorized under section 835(a) of the PHS Act, as amended, or any other educational loan for nurse training costs; (3) enters into an agreement to serve as a full-time registered or advanced practice nurse for a period of not less than two years in an eligible health facility; and (4) is a U.S. citizen, U.S. national, or a permanent legal resident of the United States.

An "eligible health facility" is defined as: (1) An Indian Health Service health center; (2) a Native Hawaiian health center; (3) a public hospital (operated by a State, county, or local government); (4) a health center funded under section 330 of the PHS Act (including community, migrant, homeless, and public housing centers); (5) a rural

health clinic under Section 1861(aa)(2) of the Social Security Act; or (6) a public or nonprofit private health facility determined by the Secretary to have a critical shortage of nurses.

For Fiscal Year 2002, the Secretary has defined health facilities with a critical shortage of nurses as any public or nonprofit private health facility: (1) On the NELRP's Fiscal Year 2002 list of facilities with a critical shortage of nurses; (2) located in a county on the NELRP's Fiscal Year 2002 list of counties with a shortage of nurses; (3) located in a currently designated whole county health professional shortage area (HPSA) or (4) classified as one of the following regardless of its location: a public health department, nursing home or rehabilitation center.

Funding Preference: A funding preference is defined as the funding of a specific category or group of approved applicants ahead of other categories or groups of applicants. The following preferences apply to the NELRP applicants:

A. As provided in section 846(e) of the PHS Act, as amended, first preference will be given to qualified applicants with the greatest financial need who agree to serve in eligible health facilities located in a county on the NELRP's Fiscal Year 2002 list of counties with a shortage of nurses.

Applicants whose total qualifying loans are 40% or greater of their annualized salary will meet the greatest financial need requirement of the funding preference.

B. Remaining funds will be awarded in the following order: (1) To qualified applicants who are employed at an eligible health facility located in a county with a shortage of nurses regardless of the applicant's financial need; (2) to qualified applicants employed at an eligible health facility not located in a county with a shortage of nurses who demonstrate greatest financial need; and (3) other qualified applicants who are serving in States that received few or no new NELRP participants.

Estimated Amount of Available Funds: Up to \$8,000,000 will be available in Fiscal Year 2002 for this program.

Estimated Number of Awards: It is estimated that 445 Loan Repayment Contracts will be awarded in Fiscal Year 2002 for this program.

Application Requests, Availability, Dates and Addresses: Applicants may register online at <http://bhpr.hrsa.gov/nursing> for application guidance and/or lists of eligible health facilities, nurse shortage counties, and HPSAs by following the instructions on the Web

page. Instructions for submitting applications electronically will also be available on the Web. Application guidance will be available for downloading via the Web on April 9, 2002. Applicants who register online will automatically be sent information regarding the application guidance and/or lists of eligible health facilities, nurse shortage counties, and HPSAs.

Applicants may also request a hard copy of the application materials and/or lists of eligible health facilities, nurse shortage counties, and HPSAs by calling (866) 813-3753.

In order to be considered, applications for loan repayment must be submitted to the Division of Nursing (NELRP), Bureau of Health Professions, HRSA, Room 9-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Applications must be postmarked by June 14, 2002. Applications postmarked after the deadline date or sent to any address other than the Rockville, Maryland address may be returned to the applicant and not processed.

FOR FURTHER INFORMATION CONTACT: Ms. Jacqueline Brown, e-mail at jbrown1@hrsa.gov; Ms. Leola Bennett, e-mail at lbennett@hrsa.gov; or Ms. Robin Ingram, e-mail at ringram@hrsa.gov, Division of Nursing, Bureau of Health Professions, HRSA, Room 9-36, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Central telephone is (301) 443-3232. Fax number is (301)443-0791.

Paperwork Reduction Act: The Application for Nursing Education Loan Repayment Program has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 0915-0140.

The program is not subject to the provision of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100). This program is also not subject to the Public Health Systems Reporting Requirements.

Dated: March 29, 2002.

Elizabeth M. Duke,

Administrator.

[FR Doc. 02-8496 Filed 4-8-02; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Refugee Resettlement Program: Proposed Notice of Allocations to States of FY 2002 Funds for Refugee Social Services

AGENCY: Office of Refugee Resettlement (ORR), ACF, HHS.

ACTION: Proposed notice of allocations to States of FY 2002 funds for refugee social services.

SUMMARY: This notice establishes the proposed allocations to States of FY 2002 funds for social services under the Refugee Resettlement Program (RRP). In the final notice, amounts could be adjusted slightly based on final adjustments in FY 2001 arrivals in some States.

DATES: Comments on this notice must be received by May 9, 2002.

ADDRESSES: Address written comments, in duplicate, to: Barbara R. Chesnik, Office of Refugee Resettlement, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447. Due to delays in mail delivery to Federal offices, a copy of comments should also be faxed to: (202) 401-5487.

FOR FURTHER INFORMATION CONTACT: Barbara R. Chesnik, Division of Refugee Self-Sufficiency, telephone: (202) 401-4558, e-mail: bchesnik@acf.dhhs.gov.

SUPPLEMENTARY INFORMATION:

I. Amounts For Allocation

The Office of Refugee Resettlement (ORR) has available \$158,600,000 in FY 2002 refugee social service funds as part of the FY 2002 appropriation for the Department of Health and Human Services (Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2002, Pub. L. No. 107-116).

The FY 2002 House Appropriations Committee Report (H.R. Rept. No. 107-229) reads as follows with respect to social services funds:

The bill provides \$158,621,000 for social services, \$15,000,000 more than the fiscal year 2001 appropriation and the budget request. Funds are distributed by formula as well as through the discretionary grant making process for special projects. The bill includes \$15,000,000 to increase educational support to schools with a significant proportion of refugee children, consistent with previous support to schools heavily impacted by large concentration of refugees.

The Committee agrees that \$19,000,000 is available for assistance to serve communities affected by the Cuban and Haitian entrants