

and sensitivity to the diverse needs of runaway and homeless youth who represent particular ethnic and racial backgrounds and sexual orientations. Applicants are encouraged to describe the type, capacity and staff supervision of the shelter that will be available for youth.

Applicants must refer to the specific evaluation criteria for each competitive area contained in the full Program Announcement in order to adequately prepare their applications.

Criterion 4: Staff and Position Data (10 points)

Applicants will be judged on whether they provide a resume and biographical sketch for each key person appointed and a job description for each vacant key position. A biographical sketch will also be required for new key staff as appointed. Applicants will be expected to list organizations and consultants who will work on the program along with a short description of the nature of their effort or contribution.

Applicants will be expected to provide information on plans for training project staff as well as staff of cooperating organizations and individuals and state the expected or estimated ratio of staff to youth.

Applicants must refer to the specific evaluation criteria for each competitive area contained in the full Program Announcement in order to adequately prepare their applications.

Criterion 5: Organizational Profile (10 points plus 5 possible bonus points)

Applicants will be expected to provide information on the applicant organization(s) and cooperating partners such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants. Any non-profit organization submitting an application must submit proof of its non-profit status in its application at the time of submission. Bonus points shall be awarded to applicant organizations who have demonstrated experience in providing services to runaway, homeless and street youth.

Applicants will be expected to provide a plan for project continuance beyond grant support, including a plan for securing resources and continuing project activities after Federal assistance has ceased and an annotated listing of applicant's funding sources. Such plans should include written agreements, if applicable, between grantees and subgrantees or subcontractors or other cooperating and letters of support and statements from community, public and

commercial leaders that support the project proposed for funding.

Applicants must refer to the specific evaluation criteria for each competitive area contained in the full Program Announcement in order to adequately prepare their applications.

Criterion 6: Budget and Budget Justification (10 points)

Applicants will be expected to provide a detailed line item budget and a narrative budget justification that describes how the categorical costs are derived. Applicants will be judged on how clearly they discuss the necessity, reasonableness, and allocability of the proposed costs and how clearly they describe the fiscal control and accounting procedures that will be used to ensure prudent use, proper disbursement and accurate accounting of funds received.

Applicants must refer to the specific evaluation criteria for each competitive area contained in the full Program Announcement in order to adequately prepare their applications.

Part 2. Required Notification of the Single Point of Contact

Most portions of this program are covered under Executive Order 12372, Intergovernmental Review of Federal Programs, and 45 CFR part 100, Intergovernmental Review of Department of Health and Human Services Program and Activities. Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

All States and Territories except Alabama, Alaska, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, New York, Ohio, Oklahoma, Oregon, Palau, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, and American Samoa have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-three jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the

applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Application for Federal Assistance, Standard Form 424, item 16.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards. A list of the Single Points of Contact for each State and Territory can be found on the web site <http://www.whitehouse.gov/omb/grants/spoc.html> or by calling the ACYF Operations Center at 1-800-351-2293.

Dated: March 2, 2001.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Child Support Enforcement; Statement of Organization, Functions and Delegations; Correction

AGENCY: Office of Child Support Enforcement (OCSE), ACF, DHHS.

ACTION: Notice; correction.

SUMMARY: This notice corrects the Office of Child Support Enforcement Statement of Organization, Functions and Delegations published in the **Federal Register** on January 29, 2001 (66 FR 8116). It corrects the standard administrative codes, and the responsibilities of one Division; and makes a technical correction.

FOR FURTHER INFORMATION CONTACT: Marilyn R. Cohen, Administration for Children and Families, Office of Child Support Enforcement, 370 L'Enfant Promenade, SW., Washington, DC 20447, Phone: 202-401-5366.

Correction

In the cited issuance on page 8117 in section b. KF.10 Organization, correct the standard administrative codes by removing them and replacing them as follows:

Office of Director/Deputy Director/
Commissioner (KFA)
Office of Audit (KFAA)
Office of Grants Management (KFAB)
Office of Mandatory Grants (KFAC)
Office of the Deputy Commissioner
(KFB)
Office of Automation and Program
Operations (KFB1)

Division of Federal Systems (KFB11)
 Division of State and Tribal Systems (KFB12)
 Division of Management Services (KFB2)
 Division of Consumer Services (KFB3)
 Division of Planning, Research, and Evaluation (KFB4)
 Division of Policy (KFB5)
 Division of Special Staffs (KFB6)
 Division of State, Tribal and Local Assistance (KFB7)

Description of Division/Office Changes

In addition, we are making a technical correction by removing the last word of the first paragraph on page 8119, "Tries" and replacing it with "Tribes."

Also, on page 8119 we are removing in its entirety paragraph KFB6. Division of State, Tribal, and Local Assistance and replacing it with the following:

KFB6. Division of State, Tribal and Local Assistance, in concert with regional offices, provides information and assistance on CSE operations. It provides national direction and leadership for training and technical assistance activities and regional operations to increase CSE program effectiveness both at Federal and State/tribal levels; develops guides and resource materials and serves as a clearinghouse for specialized program techniques for use by ACF regional offices and States and tribes. The Division, through its Technical Assistance Branch, ensures the transfer of best practices among States/tribes and local CSE agencies and coordinates technical assistance nationally. The Division operates a national CSE training center which includes the operation of the National Electronic Resource System; provides logistical support for both training events and meetings; and monitors contracts with organizations affiliated with child support enforcement programs in the areas of training and technical assistance. The Division, through the Special Initiatives Branch, provides outreach and liaison services to a variety of special interest populations.

Dated: March 2, 2001.

Diann Dawson,

Acting Principal Deputy Assistant Secretary, Administration for Children and Families.

[FR Doc. 01-5758 Filed 3-7-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2636]

Guidance for Industry on Levothyroxine Sodium; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Levothyroxine Sodium: Questions and Answers." The guidance is intended to answer questions concerning applications for orally administered levothyroxine sodium drug products.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Drug Information Branch (HFD 210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD 7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 594 2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Levothyroxine Sodium: Questions and Answers." In the **Federal Register** of August 18, 1999 (64 FR 44935), FDA announced the availability of a draft version of this guidance. The August 18, 1999, document gave interested persons 60 days to submit comments. FDA has revised the guidance in response to comments. Among the revisions being made is that FDA has extended the deadline for levothyroxine sodium drug products to have approved applications from August 14, 2000, to August 14, 2001. This extension was announced in

the **Federal Register** on April 26, 2000 (65 FR 24488).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on issues concerning applications, including applications under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)), for levothyroxine sodium. 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, at any time, submit written comments on the 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 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 <http://www.fda.gov/cder/guidance/index.htm>.

Dated: March 1, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01-5609 Filed 3-7-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1149]

Guidance for Industry on Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro