The collections of information in 21 CFR 211.100, 211.160, and 211.165(e) have been approved under OMB Control No. 0910–0139; 21 CFR 312.23(a) and (b), 312.32(c), and Form FDA 1571 have been approved under OMB Control No. 0910–0014; and 21 CFR part 1271 has been approved under OMB Control No. 0910–0559.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/cber/guidelines.htm or http://www.regulations.gov.


Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. E8–7588 Filed 4–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Guidance for Industry on Blue Bird Medicated Feed Labels; 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 “Blue Bird Medicated Feed Labels.” This guidance provides new animal drug application (NADA) sponsors with the Center for Veterinary Medicine’s current thinking on what constitutes recommended content and format of representative labels for new animal drugs intended for use in the manufacture of medicated feeds.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Submit one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dragan Momcilovic, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6856, e-mail: dragan.momcilovic@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 30, 2006 (71 FR 63328), FDA published a notice of availability for a draft guidance entitled “Draft Guidance for Industry: Blue Bird Medicated Feed Labels” giving interested persons until January 16, 2007, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated October 30, 2006. This Level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents the agency’s current thinking on the topic. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 514.1(b)(3) have been approved under OMB control number 0910–0032.

III. Comments

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individual proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Proposed Project: Health Education Assistance Loan (HEAL) Program: Lender’s Application for Insurance Claim Form and Request for Collection Assistance Form (OMB No. 0915–0036) — Extension

The HEAL program provided federally insured loans to students in certain health professions to pay for their educational costs. HEAL Lenders use the Lender’s Application for Insurance Claim to request payment from the Federal Government for...
federally insured loans lost due to borrower’s death, disability, bankruptcy, or default. The Request for Collection Assistance form is used by HEAL lenders to request Federal assistance with the collection of delinquent payments from HEAL borrowers.

The burden estimates are as follows:

<table>
<thead>
<tr>
<th>Form</th>
<th>Number of respondents</th>
<th>Responses per respondent</th>
<th>Total responses</th>
<th>Hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lender’s Application for Insurance Claim Form 510</td>
<td>17</td>
<td>25</td>
<td>425</td>
<td>.5</td>
<td>213</td>
</tr>
<tr>
<td>Request for Collection Assistance Form 513</td>
<td>17</td>
<td>550</td>
<td>9,350</td>
<td>.167</td>
<td>1,561</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td></td>
<td>9,775</td>
<td></td>
<td>1,774</td>
</tr>
</tbody>
</table>

Send comments to Susan G. Queen, PhD, HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 7, 2008.
Alexandra Huttinger, 
Director, Division of Policy Review and Coordination.

[FR Doc. E8–7634 Filed 4–9–08; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

“Low Income Levels” Used for Various Health Professions and Nursing Programs Included in Titles III, VII, and VIII of the Public Health Service Act

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is updating income levels used to identify a “low income family” for the purpose of determining eligibility for programs that provide health professions and nursing training for individuals from disadvantaged backgrounds. These various programs are included in Titles III, VII, and VIII of the Public Health Service Act.

The Department periodically publishes in the Federal Register low income levels used to determine eligibility for grants and cooperative agreements to institutions providing training for (1) Disadvantaged individuals, (2) individuals from disadvantaged backgrounds, or (3) individuals from “low income” families.

SUPPLEMENTARY INFORMATION: The various health professions and nursing grant and cooperative agreement programs that use the low-income levels to determine whether an individual is from an economically disadvantaged background in making eligibility and funding determinations generally make awards to: Accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health professions, chiropractic, public or private nonprofit schools which offer graduate programs in behavioral health and mental health practice, and other public or private nonprofit health or education entities to assist the disadvantaged to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for disadvantaged students.

Low Income Levels

The Secretary defines a “low income family” for programs included in Titles III, VII, and VIII of the Public Health Service Act as having an annual income that does not exceed 200 percent of the Department’s poverty guidelines. A “family” is a group of two or more individuals related by birth, marriage, or adoption who live together or an individual who is not living with any relatives. Most HRSA programs use the income of the student’s parents to compute low income status, while a few programs, depending upon the legislative intent of the program, programmatic purpose of the low income level, as well as the age and circumstances of the average participant, will use the student’s family as long as he or she is not listed as a dependent upon the parents’ tax form. Each program will announce the rationale and choice of methodology for determining low income levels in their program guidance. The Department’s poverty guidelines are based on poverty thresholds published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index.

The Secretary annually adjusts the low income levels based on the Department’s poverty guidelines and makes them available to persons responsible for administering the applicable programs. The income figures below have been updated to reflect increases in the Consumer Price Index through December 31, 2007.

<table>
<thead>
<tr>
<th>Size of parents’ family*</th>
<th>Income level**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$20,800</td>
</tr>
<tr>
<td>2</td>
<td>28,000</td>
</tr>
<tr>
<td>3</td>
<td>35,200</td>
</tr>
<tr>
<td>4</td>
<td>42,400</td>
</tr>
<tr>
<td>5</td>
<td>49,600</td>
</tr>
<tr>
<td>6</td>
<td>56,800</td>
</tr>
<tr>
<td>7</td>
<td>64,000</td>
</tr>
<tr>
<td>8</td>
<td>71,200</td>
</tr>
</tbody>
</table>

* Includes only dependents listed on Federal income tax forms. Some programs will use the student’s family rather than his or her parents' family.

** Adjusted gross income for calendar year 2007.

Elizabeth M. Duke, 
Administrator.

[FR Doc. E8–7579 Filed 4–9–08; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

Dates and Times: May 7, 2008; 8:30 a.m. to 3 p.m.; May 9, 2008, 8:30 a.m. to 3 p.m. 


Status: The meeting will be open to the public.

Purpose: The Committee will focus on rural issues and how the Title VII Interdisciplinary, Community-Based Training Grant Programs identified under sections 751–756, Part D of the Public Health Service...