ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 4, 2001 (66 FR 17907). The document announced the anticipated availability of funds for cooperative agreements to study adverse affects of drugs marketed in the United States and its territories. The document was published with some inadvertent errors. This document corrects those errors.

DATES: Submit applications by June 4, 2001.

ADDRESSES: Application kits are available from, and completed applications should be submitted to Rosemary T. Springer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7182.

Note: Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20852. Please DO NOT send applications to the Center for Scientific Review (CSR), National Institutes of Health. Applications mailed to CSR and not received by FDA in time for orderly processing will be returned to the applicant without consideration. Application forms can also be found at http://www.nih.gov/grants/phs398/forms-toc.html.

FOR FURTHER INFORMATION CONTACT: Rosemary T. Springer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7182.

SUPPLEMENTARY INFORMATION: In FR Doc. 01–8246, appearing on page 17907 in the **Federal Register** of Wednesday, April 4, 2001, the following corrections are made:

1. On page 17910, in the first column, section VI.B.1.*b* is corrected to read as follows:

b. Size (70 points). Applicants should list number of patients enrolled in their database as of December 31, 2000.

- >3 million covered lives (70 points)
- >2.5 to 3 million covered lives (40 points)
- >2 to 2.5 million covered lives (30 points)
- >1.5 to 2 million covered lives (10 points)

2. On page 17910, in the first column, section VI.B.1.*c* is corrected to read as follows:

c. Duration (55 points). The calender time-period for which detailed patient longitudinal data are available and linked for routine, day-to-day analysis from at least 80 percent of the multiple State sites.

- <5 years of data online (0 points)
- 5 years of data online (25 points)
- 6 points for each additional year beyond 5 years of online data to a possible total of 55 points

3. On page 17910, in the third column, section VI.B.2. is corrected to read as follows:

2. New Molecular Entity (NME) Identification (200 points)

In table 1 of this document, 40 recently approved NMEs are listed. Applicants should respond with the number of unique patients in their system with at least 1 outpatient prescription for each of the 40 drug products listed in table 1. For each drug, points will be awarded by the review panel according to the following schedule:

- >25,000 exposed patients (5 points)
- 20,001 to 25,000 exposed patients (4 points)
- 15,001 to 20,000 exposed patients (3 points)
- 10,001 to 15,000 exposed patients (2 points)
- 5,001 to 10,000 exposed patients (1 point)
- 5,000 or fewer exposed patients (0 points).

Dated: April 17, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–9949 Filed 4–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0162]

Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements; 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 ''Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements.'' This draft guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements directed toward consumers (DTC) in print media contain adequate risk disclosure. FDA does not intend to object to the use of certain FDA-approved patient labeling, reprinted exactly as approved, to fulfill the requirement that DTC print advertisements contain a brief summary of the product's risks.

DATES: Submit written comments on the draft guidance by July 23, 2001. 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; or to 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 800–835–4709. Submit written comments on the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Nancy M. Ostrove, Center for Drug Evaluation and Research (HFD–42), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828.

Regarding prescription human biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements.'' The draft guidance describes how sponsors can use certain FDA-approved patient labeling to fulfill the requirement that prescription drug and biological product advertisements DTC in print media contain adequate risk disclosure.

The requirement that all prescription drug and biological product advertisements disclose product risks comes from section 502(n) of the Federal Food, Drug, and Cosmetic Act

(the act) (21 U.S.C. 352(n)). This section of the act requires that advertisements for prescription drugs and biological products include a true statement of information ''in brief summary'' about the benefits and risks of using the advertised product. This is often called the ''brief summary'' requirement. The prescription drug advertising regulations (21 CFR 202.1(e)(3)(iii)) specify that the information about risks include every risk in the advertised drug's approved product labeling.

Some prescription drug and biological products have FDA-approved patient labeling that contains information that is most important for the safe and effective use of these products in language consumers are likely to understand. The draft guidance specifies that FDA does not intend to object to the use of certain FDA-approved patient labeling, reprinted exactly as approved, to fulfill the brief summary requirement for DTC print advertisements. The draft guidance describes the characteristics that such patient labeling should have to be used to fulfill the brief summary requirement.

This draft guidance is being issued as a level 1 guidance, consistent with FDA's good guidance practices regulations (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on using FDA-approved patient labeling in DTC print 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 statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written 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 http://www.fda.gov/cder/guidance/index.htm and at http://www.fda.gov/cber/guidelines.

Dated: April 17, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–9948 Filed 4–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2638]

Extra-Label Use of Medicated Feeds for Minor Species; Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new compliance policy guide (CPG) section 615.115 entitled ''Extra-Label Use of Medicated Feeds for Minor Species.'' The purpose of this CPG is to provide guidance to FDA personnel concerning the agency's exercise of regulatory discretion with regard to the extra-label use of medicated feeds for minor species. This CPG has been revised in response to comments received on the draft.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the CPG and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for the electronic access to the CPG section 615.115 entitled ''Extra-Label Use of Medicated Feeds for Minor Species.''

FOR FURTHER INFORMATION CONTACT: Frances M. Pell, Center for Veterinary Medicine (HFV–235), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0188, e-mail: fpell@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 25, 1999 (64 FR 46400), FDA published a notice of availability of a draft CPG entitled ''Use of Medicated Feeds for Minor Species.'' This CPG was issued as a level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September, 2000). The purpose of this CPG is to provide guidance to FDA staff concerning the agency's exercise of regulatory discretion with regard to the extra-label use of medicated feeds for minor species. The CPG represents the agency's current thinking on this subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

The agency received comments regarding this CPG and has revised the CPG in response to the comments. Following is a discussion of the issues raised by the comments.

II. The Final Guidance

The agency received 21 comments on the draft CPG. When finalizing the CPG, the agency considered the comments and, as appropriate, incorporated them into the final guidance. The final version of the CPG differs from the draft only in three areas. The first is a change in the minor species definition to reflect a corresponding change to the new animal drug regulations at 21 CFR 514.1. Sheep are now considered a minor species for all data collection purposes (see 65 FR 47668, August 3, 2000).

The second change is a minor clarification of existing provisions. The medicated feed must be manufactured and labeled in accordance with the approved conditions of use. This means that the feed cannot be reformulated in dosage, in form, or nutritional content such that it would no longer be appropriate as a feed for the species for which it is approved. For example, a medicated feed approved for chickens may not be pelleted for use in laboratory animals. An approved swine medicated feed may not be made to correspond to the nutrient requirements of pheasants or deer. All labeling must be truthful and in accordance with the approved conditions of use.

The third change is further clarification of limitations on the agency's intent to exercise regulatory discretion with regard to extra-label use of medicated feeds. If the medicated feed is to be used in a food-producing minor species, the product must be approved in a food-producing major species. The agency intends to exercise regulatory discretion only for farmed or confined species not for unconfined wildlife. In aquaculture, the agency intends to exercise regulatory discretion only for extra-label use of medicated