(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 The draft guidance specifies that FDA does not intend to object to the use of certain FDA-approved patient labeling, reprinted exactly as approved, to fulfill the brief summary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 The draft guidance describes the characteristics that such patient labeling should have to be used to fulfill the brief summary requirement.

This draft guidance is being issued as a level 1 guidance, consistent with FDA's good guidance practices regulations (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on using FDA-approved patient labeling in DTC print advertisements.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Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance.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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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

feeds already approved for an aquatic use because factors in the aquatic environment that may affect the safety and/or effectiveness of the medicated feed are so varied.

III. Availability of Medicated Feeds for Minor Species

FDA plans to continue to address the issue of lack of availability of medicated feeds for minor species. There are serious shortcomings in the legal availability of medicated feeds for minor species. These include the need for specially formulated feeds for laboratory and zoo animals and the needs of species raised in aquaculture. Future guidance will be directed specifically at these needs.

IV. Electronic Access

Persons with access to the Internet may obtain the CPG at http://www.fda.gov/cvm and http://www.fda.gov/ora.

V. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this CPG. FDA will periodically review the comments and, where appropriate, the CPG will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Dated: April 18, 2001.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–10164 Filed 4–19–01; 3:10 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Clinical Development of a Biologically Active, Epitope-Tagged Transforming Growth Factor Beta (TGF–β) Protein

The National Cancer Institute's Laboratory of Cell Regulation and Carcinogenesis (LCRC) has created and characterized a recombinant transforming growth factor-beta (TGF–β) ligand that contains the FLAG epitope tag and yet retains full biological activity.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks a Cooperative Research and Development Agreement (CRADA) Collaborator to aid NCI in the preclinical and clinical development of a tagged form of the TGF–β protein. Initial studies from LCRC demonstrate that a specific, eight-amino acid tag (known as FLAG) can be inserted in at least three different sites in the TGF–β1 molecule, without interfering with its biological activity. LCRC has made three FLAG-tagged porcine TGF–β1 constructs and the identical murine FLAG–TGF–β1 cDNAs. Each construct differs only in the location of insertion of the FLAG tag, and these include either insertion immediately following the cleavage site N-terminal in the mature, processed TGF–β molecule, or between amino acids 4 and 5 or 11 and 12 of the mature TGF–β molecule. The tagged molecule can detected by using a number of different techniques, including: Immunohistochemistry, immunoprecipitation, flow cytometry, immunofluorescence microscopy, ELISA, immunoblotting (''western''), and affinity chromatography.

DATES: Interested parties should notify NCI in writing of their interest in filing a formal proposal no later than June 22, 2001. Potential CRADA Collaborators will then have an additional thirty (30) days to submit a formal proposal. Additional proposals will be considered after the posted deadline in the event that a CRADA partner is not found during the initial posted timeperiod.

ADDRESSES: Inquiries and proposals regarding this opportunity should be addressed to Holly Symonds Clark, PhD., Technology Development Specialist (Tel. # 301–496–0477, FAX # 301–402–2117), Technology Development and Commercialization Branch, National Cancer Institute, 6120 Executive Blvd., Suite 450, Rockville, MD 20852. Inquiries directed to obtaining a patent license(s) needed for participation in the CRADA opportunity should be addressed to John Rambosek, PhD., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, (Tel. 301–496–7056, ext. 270; FAX 301–402–0220).

SUPPLEMENTARY INFORMATION: A Cooperative Research and Development Agreement (CRADA) is the anticipated joint agreement to be entered into with NCI pursuant to the Federal Technology Act of 1986, NCI seeks a CRADA Collaborator to aid LCRC in the preclinical and clinical studies of a tagged form of the TGF–β protein. The expected duration of the CRADA would be from one (1) to five (5) years.

Background Information

NCI's LCRC has produced the first epitope-tagged, biologically active version of a member of the transforming growth factor-β (TGF–β) family of proteins. Transforming growth factor-β1 (TGF–β1) is the prototype for a large family of secreted polypeptides including the three mammalian TGF–β isoforms (TGF–β1, TGF–β2, TGF–β3), the bone morphogenetic proteins (BMPs), the activins and several more distantly related factors that regulate cell growth and function. The various members of the TGF–β superfamily play roles in development, immune homeostasis, cancer progression, autoimmune disorders and wound repair. TGF–βs are produced and secreted from the cell as large latent (inactive) molecules (pro-proteins). The Latency Associated Peptide (LAP) encompasses amino acids 1 through 279 (porcine TGF–β1) of the pro-protein. Association of LAP through disulfide bonds with the mature TGF–β1 sequence keeps TGF–β in a biologically inactive form. Conversion of this pro-peptide to a biologically active form can be achieved in several ways. These include disruption of the disulfide bonds (for example, mutation of two cysteine residues involved in forming this bond), cleavage of the protein to release the smaller biologically active TGF–β (amino acids 280 through 391 in TGF–β1), or denaturation of the associated LAP by acidification or heat.

The ability to track the distribution of any exogenously administered, recombinant forms of these proteins has been restricted by the inability to distinguish between the endogenous forms of the protein produced in treated cells or tissues, and because most available antibodies exhibit some degree of cross-reactivity with related family members. LCRC's invention demonstrates a successful approach to adding an opitope tag to the mature TGF–β1 molecule. Epitope tags are short stretches of amino acids to which a specific antibody can be raised, allowing one to directly identify and track the tagged protein that has been added to a living organism or to cultured cells. Examples of useful epitope tags include FLAG, HA (hemagglutinin) and myc. In principle, any of these epitope tags could be used to tag TGF–β family members, but NCI's LCRC has been the first to identify a way to retain biological function of the molecule following addition of the tag. Thus, it will be possible to track LCRC's tagged TGF–β molecule when used in