

Dated: March 21, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01-8199 Filed 4-3-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0146]

Draft Guidance for Industry and Reviewers on How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry and reviewers (#119) entitled "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug." This draft guidance is neither final nor is it in effect at this time. This draft guidance announces the Center for Veterinary Medicine's (CVM) policy regarding the circumstances under which CVM intends to discontinue review of submissions filed during the investigation of a new animal drug, notify the sponsor that review has been discontinued, and remove the submission from the queue.

DATES: Submit written comments on the draft guidance at any time; however, comments should be submitted by July 3, 2001, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written comments 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 Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. Persons without Internet access may submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.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 requests. See the **SUPPLEMENTARY INFORMATION** section for

electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld (HFV-100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1620, e-mail: gschmer1@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the draft guidance for industry (#119) entitled "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug." This guidance announces CVM's policy regarding the circumstances under which CVM intends to discontinue review of submissions filed during the investigation of a new animal drug, notify the sponsor that review has been discontinued, and remove the submission from the queue.

CVM's Office of New Animal Drug Evaluation (ONADE) currently has a significant backlog in the number of submissions pending review. This has prompted ONADE to look at its review process. ONADE found that one of the significant inefficient uses of reviewer resources is the number of submissions received by ONADE that require significant additional information or rehabilitation in order for ONADE to complete its review. ONADE's practice has been to keep a submission "active" pending the submission of additional information from sponsors.

Instead of keeping deficient submissions "active" pending the submission of additional or revised information, ONADE intends to handle them under the policy set out in this draft guidance. If ONADE finds minor deficiencies, ONADE should request an amendment. But, if ONADE finds that a submission is significantly deficient, ONADE should notify the sponsor that it intends to discontinue review of the submission and remove it from the queue. This policy will permit ONADE to focus on reviewing quality submissions that contain all the information necessary for ONADE to evaluate the submission, thereby facilitating new animal drug approvals.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on handling deficient submissions filed during the investigation of a new animal drug. 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

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by July 3, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document 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

Copies of the draft guidance document entitled "How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug" may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/>.

Dated: March 28, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01-8200 Filed 4-3-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of April 2001.

Name: National Advisory Council on Nurse Education and Practice (NACNEP).

Date and Time: April 26, 2001; 8:30 a.m.—5 p.m.; April 27, 2001; 8:30 a.m.—3 p.m.

Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.

The meeting is open to the public.

Agenda: Invited comments from Nursing Organizations regarding nursing workforce and shortage issues followed by discussion.

NACNEP small group working sessions related to nursing workforce and practice issues with review, discussion, and endorsement of policy document and recommendations of Ad Hoc Council work group. Administrative update of relevant issues since the last Council meeting and Council discussion and vote on procedural matters.

Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Ms. Elaine G. Cohen, Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9-35, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-1405.

Dated: March 29, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01-8248 Filed 4-3-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

List of Recipients of Indian Health Scholarships under the Indian Health Scholarship Program

The regulations governing Indian Health Care Improvement Act Programs (Pub. L. 94-437) provide at 42 CFR 36.334 that the Indian Health Service shall publish annually in the **Federal Register** a list of recipients of Indian Health Scholarships, including the name of each recipient, school and tribal affiliation, if applicable. These scholarships were awarded under the authority of Sections 103 and 104 of the Indian Health Care Improvement Act, 25 U.S.C. 1613-1613a, as amended by the Indian Health Care Amendments of 1988, Pub. L. 100-713.

The following is a list of Indian Health Scholarship Recipients funded under Sections 103 and 104 for Fiscal Year 2000:

Abeita, Lynn Ann, Arizona State University, Pueblo of Isleta, NM
 Abeita, Steven John, University of New Mexico-Albuquerque, Pueblo of Isleta, NM
 Ables, Millicent Elaine, University of Kansas, Choctaw Nation of Oklahoma
 Adams, Daniel Robert, North Dakota State University, Sisseton-Wahpeton Sioux Tribe of the Lake Traverse Reservation, SD
 Alexander, Andrea Lynn, University of Central Oklahoma, Seminole Nation of Oklahoma
 Allery, Crystal Vernelle, Minot State University, Turtle Mountain Band of Chippewa Indians of North Dakota

Allery, Cynthia Ann, University of North Dakota, Turtle Mountain Band of Chippewa Indians of North Dakota
 Allery, Lonnie William, Turtle Mountain Community College, Turtle Mountain Band of Chippewa Indians of North Dakota
 Allison, Rochelle Jade, Arizona State University, Navajo Tribe of AZ, NM & UT
 Amiotte, Lowell Ralph, University of Wyoming, Oglala Sioux Tribe of the Pine Ridge Reservation, SD
 Ammesmaki, Frank P., University of South Dakota School of Medicine, Minnesota Chippewa Tribe (Fond du Lac Band), MN
 Anderson, Debbie Ann, Salish-Kootenai Community College, Confederated Salish & Kootenai Tribes of the Flathead Reservation, MT
 Anderson, Sandra Dee, Arizona State University, Navajo Tribe of AZ, NM, & UT
 Antonio, John Emery, University of New Mexico-Albuquerque, Pueblo of Laguna, NM
 Apple, Jennifer Lynn, Old Dominion University, Choctaw Nation of Oklahoma
 Arneson, Richelle Marie, University of Washington, Central Council of the Tlingit & Haida Indian Tribes
 Arnold, Delphine, University of New Mexico-Gallup, Navajo Tribe of AZ, NM & UT
 Ashley, Jeannette, New Mexico State University-Las Cruces, Navajo Tribe of AZ, NM & UT
 Ashley, Natalie Lynn, Arizona State University, Navajo Tribe of AZ, NM & UT
 Atcitty, Nichole Robin, University of New Mexico-Gallup, Navajo Tribe of AZ, NM & UT
 Bacoch, Michael, University of the Pacific School of Pharmacy, Big Pine Paiute Shoshone
 Bailor, Jeanne Lesley, Bartlesville Wesleyan College, Cherokee Nation, Oklahoma
 Barber, Tina, Northern Arizona University, Navajo Tribe of AZ, NM & UT
 Barkhurst, Kip, University of New Mexico-Albuquerque, Navajo Tribe of AZ, NM & UT
 Barnes, Carmen Rose, University of New Mexico-Albuquerque, Confederated Salish & Kootenai Tribes of the Flathead Reservation, MT
 Barnes, Kellie Elizabeth, University of Oklahoma, Chickasaw Nation, Oklahoma
 Bartholomew, Michael Lee, Dartmouth Medical School, Kiowa Indian Tribe of Oklahoma
 Bates, Vanessicia, Arizona State University, Navajo Tribe of AZ, NM & UT
 Becenti, Deann Lynn, University of New Mexico-Gallup, Navajo Tribe of AZ, NM & UT
 Begay, Andrea, Northern Arizona University, Navajo Tribe of AZ, NM & UT
 Begay, Bryant, Pima Medical Institute, Navajo Tribe of AZ, NM & UT
 Begay, Michelle, University of Arizona, Navajo Tribe of AZ, NM & UT
 Begay, Miranda, University of New Mexico College of Pharmacy, Navajo Tribe of AZ, NM, & UT
 Begay, Mirielle Rose, University of New Mexico, Navajo Tribe of AZ, NM, & UT
 Begay, Monica Calley, Colorado State University, Navajo Tribe of AZ, NM, & UT
 Begay, Pierrette Rose, Arizona State University, Navajo Tribe of AZ, NM, & UT
 Begay, Tamana Dollicia, University of the Pacific, Navajo Tribe of AZ, NM, & UT
 Begaye, Wahaila Nizhoni, University of Utah, Navajo Tribe of AZ, NM, & UT
 Behymer, Virginia May, University of Alaska-Anchorage, Aleut, AK
 Belgarde, Vita Ann, University of North Dakota, Turtle Mountain Band of Chippewa Indians of North Dakota
 Ben, Elaine Ann, University of New Mexico-Gallup, Navajo Tribe of AZ, NM, & UT
 Benally, Annisa, New Mexico Highland University, Navajo Tribe of AZ, NM, & UT
 Benally, Cheryl Lynn, Pima County Community College, Navajo Tribe of AZ, NM, & UT
 Benally, Yolanda Jean, New Mexico State University, Navajo Tribe of AZ, NM, & UT
 Bennett, Kennard Roger, Fort Lewis College, Navajo Tribe of AZ, NM, & UT
 Berg, Ida W., University of Phoenix, Navajo Tribe of AZ, NM, & UT
 Berquist, Melissa Dawn, University of North Dakota, Turtle Mountain Band of Chippewa Indians of North Dakota
 Berryhill-Baker, Tishanda Leigh, University of Utah College of Medicine, Muskogee (Creek) Nation, Oklahoma
 Betonie, Darlene Smith, University of Minnesota School of Nursing, Navajo Tribe of AZ, NM, & UT
 Beyale, Justina, Northern Arizona University, Navajo Tribe of AZ, NM, & UT
 Bighorn, Lisa Elaine, University of Denver, Assiniboine & Sioux Tribes of the Fort Peck Indian Reservation, MT
 Bighorn, Prairie Rose, Rocky Mountain College, Assiniboine & Sioux Tribes of the Fort Peck Indian Reservation, MT