controlled by persons who are responsible for the content of electronic records that are on the system). Should part 11 continue to differentiate between open systems and closed systems?

For individual controls in subpart B, we request comments on the following:

1. The part 11 guidance identified validation as one of the four areas where we intend to exercise enforcement discretion in the manner described in the guidance. Should we retain the validation provision under § 11.10(b) required to ensure that a system meets predicate rule requirements for validation?

2. The part 11 guidance identified record retention and record copying requirements as areas where we plan to exercise enforcement discretion in the manner described in the part 11 guidance. Are there any related predicate rule requirements that you believe are necessary to preserve the content and meaning of records with respect to record copying and record retention? What requirements would preserve record security and integrity and ensure that records are suitable for inspection, review, and copying by the agency?

3. Should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification, and deletion?

4. Section 11.10(k) requires appropriate controls over systems documentation. In light of how technology has developed since part 11 became effective, should part 11 be modified to incorporate concepts, such as configuration and document management, for all of a system's software and hardware?

C. Part 11 Subpart C—Electronic Signatures

Within the context of subpart C, we would like interested parties to address the following: Section 11.10(d) requires that system access be limited to authorized individuals, but it does not address the handling of security breaches where an unauthorized individual accesses the system. Should part 11 address investigations and followup when these security breaches occur?

D. Additional Questions for Comment

In addition, we invite comment on the following questions:

1. What are the economic ramifications of modifying part 11 based on the issues raised in this document?

2. Is there a need to clarify in part 11 which records are required by predicate rules where those records are not specifically identified in predicate rules? If so, how could this distinction be made?

3. In what ways can part 11 discourage innovation?

4. What potential changes to part 11 would encourage innovation and technical advances consistent with the agency's need to safeguard public health?

5. What risk-based approaches would help to ensure that electronic records have the appropriate levels of integrity and authenticity elements and that electronic signatures are legally binding and authentic?

6. The part 11 guidance announced that the agency would exercise enforcement discretion (during our re-examination of part 11) with respect to all part 11 requirements for systems that otherwise were operational prior to August 20, 1997 (legacy systems), the effective date of part 11. What are stakeholder concerns in regards to modifications made to legacy systems in use as of August 1997?

Can the use of risk mitigation and appropriate controls eliminate concerns regarding legacy systems?

7. Should part 11 address record conversion?

8. Are there provisions of part 11 that should be augmented, modified, or deleted as a result of new technologies that have become available since part 11 was issued?

V. Registration and Requests for Oral Presentations

Preregistration is not necessary if you are not speaking and plan only to attend. However, seating is limited and will be available on a first-come first-served basis.

To speak at the public meeting, you must preregister by May 12, 2004. Requests must be submitted electronically or in writing (see **ADDRESSES**). In your request to speak, you should provide the following information: (1) Specific issue that you intend to address; (2) names and addresses of all individuals that plan to participate; and (3) presentation abstract. Presentations should be limited to the topics addressed in this document. We will accept requests to speak based on the number of requests we receive, time constraints, and subjects covered. We will notify speakers of the scheduled time for their presentation before the meeting. Depending on the number of speakers, we may need to limit the time allotted for each presentation; at this point speakers should plan to limit their oral presentations to no more than 15 minutes. Speakers must submit two copies of each presentation by June 11, 2004. If you need special accommodations due to a disability, please inform the registration contact person at least 7 days in advance of the meeting.

VI. Request for Comments

Regardless of attendance at the public meeting, interested persons may submit written or electronic comments on the topics presented in this document by July 9, 2004, to the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific sections of part 11 and/or topics to which they refer. Two copies of any mailed 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 received comments may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Transcripts of the public meeting also will be available for review at the Division of Dockets Management.

Dated: April 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–7942 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Use of Radiolabeled Platelets for Assessment of In Vivo Viability of Platelet Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Use of Radiolabeled Platelets for Assessment of the In Vivo Viability of Platelet Products''. The goal of the workshop is to orient the transfusion community to a new approach for assessing the quality of platelet products through radiolabeling studies in healthy human volunteers.

Date and Time: The public workshop will be held on May 3, 2004, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at Lister Hill Auditorium, Building 38A, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *wilczek@cber.fda.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by April 23, 2004. Early registration is recommended because seating is limited to 176 participants. Registration will be done on a space available basis on the day of the workshop, beginning at 7:15 a.m. There is no registration fee.

If you need special accommodations due to a disability, please contact Joseph Wilczek (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, in co-sponsorship with the Hitchcock Foundation, is sponsoring a public workshop on the development of a new standard for assessing the in vivo quality of platelet products through radiolabeling studies. The workshop objectives are to review current methods in radiolabeling studies, to propose a new approach that will set the performance of fresh platelets as a gold standard, to present data on application of a new standard, and to discuss the development of a novel experimental protocol. The public workshop agenda is posted on FDA's Internet at *http://www.fda.gov/cber/meetings/radioplt0504.htm*.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. In addition, the transcript will be placed on FDA's Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: April 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8023 Filed 4–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0160]

Guidance for Industry: Use of Unapproved Hormone Implants in Veal Calves; 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 (#172) entitled "Use of Unapproved Hormone Implants in Veal Calves.'' This guidance outlines special measures to ensure the safety of veal in response to the identified illegal use of unapproved hormone implants in veal calves.

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

ADDRESSES: Submit written comments on the 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.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

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.

FOR FURTHER INFORMATION CONTACT: Gloria J. Dunnavan, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1168, e-mail: *gloria.dunnavan@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation in § 10.115 (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because of the agency's urgent need to provide guidance concerning veal that has been implanted with unapproved hormones. However, under GGPs, FDA requests comments on the guidance and will revise the document, if appropriate. Comments will be considered by the agency in the development of future policy.

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 applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of this guidance document may be obtained from the CVM home page (*http://www.fda.gov/cvm*) and from the Division of Dockets Management Web site (*http://www.fda.gov/ohrms/dockets/default.htm*).

Dated: April 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–8075 Filed 4–6–04; 2:25 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and