products in the EU, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologists, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Study to Marker Residue Depletion Studies to Establish Product Withdrawal Periods

The VICH Steering Committee held a meeting on November 5, 2009, and agreed that the draft guidance document entitled “Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods,” VICH GL48 should be made available for public comment. This draft VICH guidance document is one of a series developed to facilitate the mutual acceptance of residue chemistry data for veterinary drugs used in food-producing animals. This guidance was prepared after consideration of the current requirements for evaluating veterinary drug residues in the EU, Japan, the United States, Australia, New Zealand, and Canada.

As part of the approval process for veterinary medicinal products in food-producing animals, regulatory authorities recommend data from marker residue depletion studies in order to establish appropriate withdrawal periods in edible products including meat, milk, eggs, and honey. The objective of this guidance is to provide study design recommendations which will facilitate the universal acceptance of the generated residue depletion data to fulfill this recommendation.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

III. Significance of Guidance

This draft guidance, developed under the VICH process, has been revised to conform to FDA’s good guidance practices regulation (21 CFR 10.115). For example, the document has been designated “guidance” rather than “guideline.” In addition, guidance documents must not include mandatory language such as “shall,” “must,” “require,” or “requirement,” unless FDA is using these words to describe a statutory or regulatory requirement.

The draft guidance, when finalized, will represent the agency’s current thinking on this 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 applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This draft 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 sections 1–2 of the guidance have been approved under OMB control no. 0910–0032.

V. Comments

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 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.

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/AnimalVeterinary/default.htm or http://www.regulations.gov.
electronic comments to http://www.regulations.gov. See the
SUPPLEMENTARY INFORMATION section for
electronic access to the draft guidance
document.

FOR FURTHER INFORMATION CONTACT: Julia
Oriani, Center for Veterinary Medicine,
(HFV–151), Food and Drug
Administration, 7500 Standish Pl.,
Rockville, MD 20855, 240–276–8204, e-
mail: julia.oriani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background
FDA is announcing the availability of
a draft guidance for industry (#208)
entitled “Draft Guidance for Industry on
Guidances for the Validation of
Analytical Methods Used in Residue
Depletion Studies,” VICH GL49. In
recent years, many important initiatives
have been undertaken by regulatory
authorities and industry associations to
promote the international
harmonization of regulatory
requirements. FDA has participated in
efforts to enhance harmonization and
has expressed its commitment to seek
scientifically based harmonized
technical procedures for
the development of pharmaceutical
products. One of the goals of
harmonization is to identify and then
reduce differences in technical
requirements for drug development
among regulatory agencies in different
countries.

FDA has actively participated in the
International Conference on
Harmonisation of Technical
Requirements for Approval of
Pharmaceuticals for Human Use for
several years to develop harmonized
technical requirements for the approval
of human pharmaceutical and biological
products among the EU, Japan, and the
United States. The VICH is a parallel
initiative for veterinary medicinal
products. The VICH is concerned with
developing harmonized technical
requirements for the approval of
veterinary medicinal products in the
EU, Japan, and the United States, and
includes input from both regulatory and
industry representatives.

The VICH Steering Committee is
composed of member representatives
from the European Commission,
European Medicines Evaluation Agency,
European Federation of Animal Health,
Committee on Veterinary Medicinal
Products, the U.S. FDA, the U.S.
Department of Agriculture, the Animal
Health Institute, the Japanese Veterinary
Pharmaceutical Association, the
Japanese Association of Veterinary
Biologics, and the Japanese Ministry of
Agriculture, Forestry, and Fisheries.

Four observers are eligible to
participate in the VICH Steering
Committee: One representative from the
government of Australia/New Zealand,
one representative from the industry in
Australia/New Zealand, one
representative from the government of
Canada, and one representative from the
industry of Canada. The VICH
Secretariat, which coordinates the
preparation of documentation, is
provided by the International
Federation for Animal Health (IFAH).
An IFAH representative also
participates in the VICH Steering
Committee meetings.

II. Draft Guidance on the Validation of
Analytical Methods Used in Residue
Depletion Studies
The VICH Steering Committee held a
meeting on November 5, 2009, and
agreed that the draft guidance document
entitled “Draft Guidelines for the
Validation of Analytical Methods Used in
Residue Depletion Studies,” (VICH
GL49) should be made available for
public comment. This draft VICH
guidance document is one of a series
developed to facilitate the mutual
acceptance of residue chemistry data for
veterinary drugs used in food-producing
animals. This guidance was prepared
after consideration of the current
requirements for evaluating veterinary
drug residues in the EU, Japan, the
United States, Australia, New Zealand,
and Canada.

During the veterinary drug
development process, residue depletion
studies are conducted to determine the
concentration of the residue or residues
present in the edible products (tissues,
milk, eggs, or honey) of animals treated
with veterinary drugs. This information
is used in regulatory submissions
around the world. Submission of
regulatory methods (postapproval
control methods) and the validation
requirements of the regulatory methods
are usually well defined by various
regulatory agencies worldwide and may
even be defined by law. Consequently,
the VICH has difficulty harmonizing the
procedures used for validation of these
methods. However, the residue studies
are generally conducted before the
regulatory methods have been
completed. Often the in-house validated
residue methods provide the framework
for the methods submitted for regulatory
monitoring. Harmonization of the
validation requirements for
methodology used during residue
studies and submitted to the regulatory
agencies in support of the maximum
residue limits and withdrawal periods
should be achievable. It is the intent of
this document to describe a validation
procedure that is acceptable to the
regulatory bodies of the EU, Japan, the
United States, Australia, New Zealand,
and Canada for use in the residue
depression studies. This validated
method may continue on to become the
“regulatory method” but that phase of
the process will not be addressed in any
detail in these guidelines.

FDA and the VICH Expert Working
Group will consider comments about
the draft guidance document.

III. Significance of Guidance
This draft guidance, developed under
the VICH process, has been revised in
to conform to FDA’s good
For example, the document has been
designated “guidance” rather than
“guideline.” In addition, guidance
documents must not include mandatory
language such as “shall,” “must,”
“require,” or “requirement,” unless FDA
is using these words to describe a
statutory or regulatory requirement.

The draft guidance, when finalized,
will represent the agency’s current
thinking on this 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
requirements of applicable statutes and
regulations.

IV. Paperwork Reduction Act of 1995
This draft 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 sections 1–3 of this
guidance have been approved under
OMB control no. 0910–0032.

V. Comments
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
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.

VI. Electronic Access
Persons with access to the Internet
may obtain the draft guidance at either
http://www.fda.gov/AnimalVeterinary/
The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#206) entitled “Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Comparative Metabolism Studies in Laboratory Animals, VICH GL47.” This draft guidance document is intended to provide recommendations for internationally harmonized procedures to identify the metabolites of veterinary food animal drugs in laboratory animals used for toxicological testing for the purpose of comparison to the residues of the drugs in food animals.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 12, 2010.

ADDRESSES: Submit written requests for single copies of the draft 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 request.

Submit written comments on the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Oriani, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8204, e-mail: julia.orianii@fda.hhs.gov.

I. Background

FDA is announcing the availability of a draft guidance for industry (#206) entitled “Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Comparative Metabolism Studies in Laboratory Animals,” VICH GL47. In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union (EU), Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the EU, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of members representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologists, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

The VICH Steering Committee held a meeting on November 5, 2009, and agreed that the draft guidance document entitled “Draft Guidance for Industry on Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Comparative Metabolism Studies in Laboratory Animals,” VICH GL47 should be made available for public comment. This draft VICH guidance document is one of a series developed to facilitate the mutual acceptance of residue chemistry data for veterinary drugs used in food-producing animals. This guidance was prepared after consideration of the current requirements for evaluating veterinary drug residues in the EU, Japan, United States, Australia, New Zealand, and Canada.

The objective of this guidance is to provide recommendations for internationally harmonized procedures to identify the metabolites of veterinary food animal drugs in laboratory animals used for toxicological testing for the purpose of comparison to the residues of the drugs in food animals.