evaluating the quality and reliability of information and data for use in developing the VADS system contents; (3) apply the principles of pharmacology in constructing therapeutic regimens for use when approved antimicrobial products are not effective as labeled; (4) design a relational database allowing a user to efficiently search the VADS system for label and extralabel regimens based on therapeutic applications, and to then review regulatory and food safety information applicable to these regimens; and (5) subject the VADS system content to review prior to release and then constantly upgrade the content on the basis of new information and review by users.

II. Eligible Applicants

Assistance may only be provided to Iowa State University because of the following:

1. Iowa State University is the only organization that submitted an unsolicited application for the purpose stated above.
2. The project proposed by the applicant is unique and innovative in that pharmacokinetic, pharmacodynamic, clinical trial, and pathogen susceptibility information will be interpreted by clinical pharmacologists and reviewed by other experts in the appropriate fields prior to inclusion in the system. Users may either use the information as provided or examine the transparent development process used in constructing the system. In addition, by compiling available information to support prudent antimicrobial use, the VADS system will emphasize what information is not available, thereby aiding researchers in targeting research goals.
3. The team assembled to carry out the proposed work is uniquely qualified to achieve the goals of this application. Their combined experience encompasses practice in academic, general, and specialized production medicine settings as well as demonstrated competence in the application of clinical pharmacology and informatics in veterinary medicine. Support for the research team and the VADS system project has already been expressed in the form of start up funding provided by veterinary and producer organizations.

III. Funding

We anticipate that approximately $250,000 may be made available in fiscal year (FY) 2001 to support this project. If funded the award will begin sometime in FY 2001 and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Dated: December 22, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–33372 Filed 12–28–01; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0448]

International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes or provides recommendations concerning the selection of test procedures and the setting and justification of acceptance criteria for new chemical drug substances and new drug products produced from them. The guidance is intended to assist in the establishment of a single set of global specifications for new drug substances and new drug products.

DATES: Submit written comments by March 29, 2001.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Eric B. Sheinin, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2847, or Neil D. Goldman, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0377.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of November 25, 1997 (62 FR 62890), FDA published a draft tripartite guidance entitled ''Q6A Specifications: Test Procedures and

Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances.'' The notice gave interested persons an opportunity to submit comments by January 26, 1998.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on October 6, 1999.

In accordance with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000), this document has been designated a guidance, rather than a guideline.

The guidance provides recommendations on the selection of test procedures and the setting and justification of acceptance criteria for new drug substances of synthetic chemical origin, and new drug products produced from them, that have not been registered previously in the United States, the European Union, or Japan. This guidance is intended to assist in the establishment of a single set of global specifications for new drug substances and new drug products.

This guidance represents the agency's current thinking on the selection of tests procedures and the setting and justification of acceptance criteria for new chemical drug substances and new drug products. 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.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance at any time. 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 guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at http://www.fda.gov/cder/guidance/index.htm or at http://www.fda.gov/cber/publications.htm.

The text of the guidance follows:

Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances [1]

Table of Contents

1. Introduction

1.1 Objective of the Guidance

This guidance is intended to assist, to the extent possible, in the establishment of a single set of global specifications for new drug substances and new drug products. It provides guidance on the setting and justification of acceptance criteria and the selection of test procedures for new drug substances of synthetic chemical origin, and new drug products produced from them, that have not been registered previously in the United States, the European Union, or Japan.

1.2 Background

A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a drug substance or drug product should conform to be considered acceptable for its intended use. ''Conformance to specifications'' means that the drug substance and/or drug product, when tested according to the listed analytical procedures, will meet the listed acceptance criteria. Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities as conditions of approval.

Specifications are one part of a total control strategy for the drug substance and drug product designed to ensure product quality and consistency. Other parts of this strategy include thorough product characterization during development, upon which specifications are based, and adherence to good manufacturing practices (GMP's), e.g., suitable facilities, a validated manufacturing process, validated test procedures, raw materials testing, in-process testing, stability testing.

Specifications are chosen to confirm the quality of the drug substance and drug product rather than to establish full characterization, and should focus on those characteristics found to be useful in ensuring the safety and efficacy of the drug substance and drug product.

1.3 Scope of the Guidance

The quality of drug substances and drug products is determined by their design, development, in-process controls, GMP controls, process validation, and by specifications applied to them throughout development and manufacture. This guidance addresses specifications, i.e., those tests, procedures, and acceptance criteria that play a major role in assuring the quality of the new drug substance and new drug product at release and during shelf life. Specifications are an important component of quality assurance, but are not its only component. All of the factors listed above are considered necessary to ensure consistent production of drug substances and drug products of high quality.

This guidance addresses only the marketing approval of new drug products (including combination products) and, where applicable, new drug substances; it does not address drug substances or drug products during the clinical research stages of drug development. This guidance may be applicable to synthetic and semisynthetic antibiotics and synthetic peptides of low molecular weight; however, it is not sufficient to

[1] This guidance represents the Food and Drug Administration'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 the applicable statutes and regulations.

adequately describe specifications of higher molecular weight peptides and polypeptides, and biotechnological/biological products. The ICH guidance on ''Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products'' addresses guidance specifications, tests, and procedures for biotechnological/biological products. Radiopharmaceuticals, products of fermentation, oligonucleotides, herbal products, and crude products of animal or plant origin are similarly not covered.

Guidance is provided with regard to acceptance criteria that should be established for all new drug substances and new drug products, i.e., universal acceptance criteria, and those that are considered specific to individual drug substances and/or dosage forms. This guidance should not be considered all encompassing. New analytical technologies, and modifications to existing technology, are continually being developed. Such technologies should be used when justified.

Dosage forms addressed in this guidance include solid oral dosage forms, liquid oral dosage forms, and parenterals (small and large volume). This is not meant to be an all-inclusive list, or to limit the number of dosage forms to which this guidance applies. The dosage forms presented serve as models that may be applicable to other dosage forms that have not been discussed. The extended application of the concepts in this guidance to other dosage forms, e.g., to inhalation dosage forms (powders, solutions, etc.), to topical formulations (creams, ointments, gels), and to transdermal systems, is encouraged.

2. General Concepts

The following concepts are important in the development and setting of harmonized specifications. They are not universally applicable, but each should be considered in particular circumstances. This guidance presents a brief definition of each concept and an indication of the circumstances under which it may be applicable. Generally, proposals to implement these concepts should be justified by the applicant and approved by the appropriate regulatory authority before being put into effect.

2.1 Periodic or Skip Testing

Periodic or skip testing is the performance of specified tests at release on preselected batches and/or at predetermined intervals, rather than on a batch-by-batch basis, with the understanding that those batches not being tested still meet all acceptance criteria established for that product. This represents a less than full schedule of testing and should therefore be justified and presented to and approved by the regulatory authority prior to implementation. This concept may be applicable to, for example, residual solvents and microbiological testing for solid oral dosage forms. It is recognized that only limited data may be available at the time of submission of an application (see section 2.5). This concept should therefore generally be implemented postapproval. When tested, any failure to meet acceptance criteria established for the periodic test should be handled by proper notification of the appropriate regulatory authority(ies). If these data demonstrate a need to restore routine testing, then batch-by-batch release testing should be reinstated.

2.2 Release vs. Shelf-Life Acceptance Criteria

The concept of different acceptance criteria for release vs. shelf-life specifications applies to drug products only; it pertains to the establishment of more restrictive criteria for the release of a drug product than are applied to the shelf life. Examples where this may be applicable include assay and impurity (degradation product) levels. In Japan and the United States, this concept may only be applicable to in-house criteria, and not to the regulatory release criteria. Thus, in these regions, the regulatory acceptance criteria are the same from release throughout shelf life; however, an applicant may choose to have tighter in-house limits at the time of release to provide increased assurance to the applicant that the product will remain within the regulatory acceptance criteria throughout its shelf life. In the European Union there is a regulatory requirement for distinct specifications for release and for shelf life where different.

2.3 In-Process Tests

In-process tests, as presented in this guidance, are tests that may be performed during the manufacture of either the drug substance or drug product, rather than as part of the formal battery of tests that are conducted prior to release.

In-process tests that are only used for the purpose of adjusting process parameters within an operating range, e.g., hardness and friability of tablet cores that will be coated and individual tablet weights, are not included in the specification.

Certain tests conducted during the manufacturing process, where the acceptance criterion is identical to or tighter than the release requirement, (e.g., pH (hydrogen-ion concentration) of a solution) may be sufficient to satisfy specification requirements when the test is included in the specification. However, this approach should be validated to show that test results or product performance characteristics do not change from the in-process stage to finished product.

2.4 Design and Development Considerations

The experience and data accumulated during the development of a new drug substance or product should form the basis for the setting of specifications. It may be possible to propose excluding or replacing certain tests on this basis. Some examples are:

- Microbiological testing for drug substances and solid dosage forms that have been shown during development not to support microbial viability or growth (see Decision Trees #6 and #8).
- Extractables from product containers where it has been reproducibly shown that either no extractables are found in the drug product or the levels meet accepted standards for safety.
- Particle size testing may fall into this category, may be performed as an in-process test, or may be performed as a release test, depending on its relevance to product performance.
- Dissolution testing for immediate release solid oral drug products made from highly water soluble drug substances may be replaced by disintegration testing, if these products have been demonstrated during development to have consistently rapid drug release characteristics (see Decision Trees #7(1) through #7(2)).

2.5 Limited Data Available at Filing

It is recognized that only a limited amount of data may be available at the time of filing, which can influence the process of setting acceptance criteria. As a result, it may be necessary to propose revised acceptance criteria as additional experience is gained with the manufacture of a particular drug substance or drug product (example: acceptance limits for a specific impurity). The basis for the acceptance criteria at the time of filing should necessarily focus on safety and efficacy.

When only limited data are available, the initially approved tests and acceptance criteria should be reviewed as more information is collected, with a view towards possible modification. This could involve loosening, as well as tightening, acceptance criteria, as appropriate.

2.6 Parametric Release

Parametric release can be used as an operational alternative to routine release testing for the drug product in certain cases, when approved by the regulatory authority. Sterility testing for terminally sterilized drug products is one example. In this case, the release of each batch is based on satisfactory results from monitoring specific parameters, e.g., temperature, pressure, and time during the terminal sterilization phase(s) of drug product manufacturing. These parameters can generally be more accurately controlled and measured, so they are more reliable in predicting sterility assurance than is end-product sterility testing. Appropriate laboratory tests (e.g., chemical or physical indicator) may be included in the parametric release program. It is important to note that the sterilization process should be adequately validated before parametric release is proposed, and maintenance of a validated state should be demonstrated by revalidation at established intervals. When parametric release is performed, the attribute that is indirectly controlled (e.g., sterility), together with a reference to the associated test procedure, still should be included in the specifications.

2.7 Alternative Procedures

Alternative procedures are those that may be used to measure an attribute when such procedures control the quality of the drug substance or drug product to an extent that is comparable or superior to the official procedure. Example: For tablets that have been shown not to degrade during manufacture, it may be permissible to use a spectrophotometric procedure for release as opposed to the official procedure, which is chromatographic. However, the chromatographic procedure should still be used to demonstrate compliance with the acceptance criteria during the shelf life of the product.

2.8 Pharmacopeial Tests and Acceptance Criteria

References to certain procedures are found in pharmacopeias in each region. Wherever they are appropriate, pharmacopeial procedures should be used. Whereas differences in pharmacopeial procedures and/or acceptance criteria have existed among the regions, a harmonized specification is possible only if the procedures and acceptance criteria defined are acceptable to regulatory authorities in all regions.

The full utility of this guidance is dependent on the successful completion of harmonization of pharmacopeial procedures for several attributes commonly considered in the specification for new drug substances or new drug products. The Pharmacopoeial Discussion Group (PDG) of the European Pharmacopeia, the Japanese Pharmacopoeia (JP), and the United States Pharmacopeia has expressed a commitment to achieving harmonization of the procedures in a timely fashion.

Where harmonization has been achieved, an appropriate reference to the harmonized procedure and acceptance criteria is considered acceptable for a specification in all three regions. For example, after harmonization, sterility data generated using the JP procedure, as well as the JP procedure itself and its acceptance criteria, will be considered acceptable for registration in all three regions. To signify the harmonized status of these procedures, the pharmacopeias have agreed to include a statement in their respective texts that indicates that the procedures and acceptance criteria from all three pharmacopeias are considered equivalent and are, therefore, interchangeable.

Since the overall value of this guidance is linked to the extent of harmonization of the analytical procedures and acceptance criteria of the pharmacopeias, it is agreed by the members of the Q6A expert working group that none of the three pharmacopeias should change a harmonized monograph unilaterally. According to the PDG procedure for the revision of harmonized monographs and chapters, ''no pharmacopoeia shall revise unilaterally any monograph or chapter after sign-off or after publication.''

2.9 Evolving Technologies

New analytical technologies, and modifications to existing technology, are continually being developed. Such technologies should be used when they are considered to offer additional assurance of quality, or are otherwise justified.

2.10 Impact of Drug Substance on Drug Product Specifications

In general, it should not be necessary to test the drug product for quality attributes uniquely associated with the drug substance. Example: It is normally not considered necessary to test the drug product for synthesis impurities that are controlled in the drug substance and are not degradation products. Refer to the ICH guidance on ''Q3B Impurities in New Drug Products'' for detailed information.

2.11 Reference Standard

A reference standard, or reference material, is a substance prepared for use as the standard in an assay, identification, or purity test. It should have a quality appropriate to its use. It is often characterized and evaluated for its intended purpose by additional procedures other than those used in routine testing. For new drug substance reference standards intended for use in assays, the impurities should be adequately identified and/or controlled, and purity should be measured by a quantitative procedure.

3. Guidance

3.1 Specifications: Definition and Justification

3.1.1 Definition of Specifications

A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a new drug substance or new drug product should conform to be considered acceptable for its intended use. ''Conformance to specifications'' means that the drug substance and/or drug product, when tested according to the listed analytical procedures, will meet the listed acceptance criteria. Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities as conditions of approval.

It is possible that, in addition to release tests, a specification may list in-process tests as defined in section 2.3, periodic or skip tests, and other tests that are not always conducted on a batch-by-batch basis. In such cases the applicant should specify which tests are routinely conducted batch by batch, and which tests are not, with an indication and justification of the actual testing frequency. In this situation, the drug substance and/or drug product should meet the acceptance criteria if tested.

It should be noted that changes in the specification after approval of the application may need prior approval by the regulatory authority.

3.1.2 Justification of Specifications

When a specification is first proposed, justification should be presented for each procedure and each acceptance criterion included. The justification should refer to relevant development data, pharmacopeial standards, test data for drug substances and drug products

used in toxicology and clinical studies, and results from accelerated and long-term stability studies, as appropriate. Additionally, a reasonable range of expected analytical and manufacturing variability should be considered. It is important to consider all of this information.

Approaches other than those set forth in this guidance may be applicable and acceptable. The applicant should justify alternative approaches. Such justification should be based on data derived from the new drug substance synthesis and/or the new drug product manufacturing process. This justification may consider theoretical tolerances for a given procedure or acceptance criterion, but the actual results obtained should form the primary basis for whatever approach is taken.

Test results from stability and scaleup/validation batches, with emphasis on the primary stability batches, should be considered in setting and justifying specifications. If multiple manufacturing sites are planned, it may be valuable to consider data from these sites in establishing the initial tests and acceptance criteria. This is particularly true when there is limited initial experience with the manufacture of the drug substance or drug product at any particular site. If data from a single representative manufacturing site are used in setting tests and acceptance criteria, product manufactured at all sites should still comply with these criteria.

Presentation of test results in graphic format may be helpful in justifying individual acceptance criteria, particularly for assay values and impurity levels. Data from development work should be included in such a presentation, along with stability data available for new drug substance or new drug product batches manufactured by the proposed commercial processes. Justification for proposing exclusion of a test from the specification should be based on development data and on process validation data (where appropriate).

3.2 Universal Tests/Criteria

Implementation of the recommendations in the following section should take into account the ICH guidances ''Q2A Text on Validation of Analytical Procedures'' and ''Q2B Validation of Analytical Procedures: Methodology.''

3.2.1 New Drug Substances

The following tests and acceptance criteria are considered generally applicable to all new drug substances.

(a) *Description:* A qualitative statement about the state (e.g., solid, liquid) and color of the new drug substance. If any of these characteristics change during storage, this change should be investigated and appropriate action taken.

(b) *Identification:* Identification testing should optimally be able to discriminate between compounds of closely related structure that are likely to be present. Identification tests should be specific for the new drug substance, e.g., infrared spectroscopy (IR). Identification solely by a single chromatographic retention time, for example, is not regarded as being specific. However, the use of two chromatographic procedures, where the separation is based on different principles or a combination of tests into a single procedure, such as HPLC (high-pressure liquid chromatography)/UV (ultraviolet) diode array, HPLC/MS (mass spectroscopy), or GC (gas chromatography)/MS is generally acceptable. If the new drug substance is a salt, identification testing should be specific for the individual ions. An identification test that is specific for the salt itself should suffice.

New drug substances that are optically active may also need specific identification testing or performance of a chiral assay. Please refer to section 3.3.1(d) in this guidance for further discussion of this topic.

(c) *Assay:* A specific, stability-indicating procedure should be included to determine the content of the new drug substance. In many cases it is possible to employ the same procedure (e.g., HPLC) for both assay of the new drug substance and quantitation of impurities.

In cases where use of a nonspecific assay is justified, other supporting analytical procedures should be used to achieve overall specificity. For example, where titration is adopted to assay the drug substance, the combination of the assay and a suitable test for impurities should be used.

(d) *Impurities:* Organic and inorganic impurities and residual solvents are included in this category. Refer to the ICH guidances on ''Q3A Impurities in New Drug Substances'' and ''Q3C Impurities: Residual Solvents'' for detailed information.

Decision Tree #1 addresses the extrapolation of meaningful limits on impurities from the body of data generated during development. At the time of filing it is unlikely that sufficient data will be available to assess process consistency. Therefore it is considered inappropriate to establish acceptance criteria that tightly encompass the batch data at the time of filing (see section 2.5).

3.2.2 New Drug Products

The following tests and acceptance criteria are considered generally applicable to all new drug products:

(a) *Description:* A qualitative description of the dosage form should be provided (e.g., size, shape, and color). If any of these characteristics change during manufacture or storage, this change should be investigated and appropriate action taken. The acceptance criteria should include the final acceptable appearance. If color changes during storage, a quantitative procedure may be appropriate.

(b) *Identification:* Identification testing should establish the identity of the new drug substance(s) in the new drug product and should be able to discriminate between compounds of closely related structure that are likely to be present. Identity tests should be specific for the new drug substance, e.g., infrared spectroscopy. Identification solely by a single chromatographic retention time, for example, is not regarded as being specific. However, the use of two chromatographic procedures, where the separation is based on different principles, or a combination of tests into a single procedure, such as HPLC/UV diode array, HPLC/MS, or GC/MS, is generally acceptable.

(c) *Assay:* A specific, stability-indicating assay to determine strength (content) should be included for all new drug products. In many cases it is possible to employ the same procedure (e.g., HPLC) for both assay of the new drug substance and quantitation of impurities. Results of content uniformity testing for new drug products can be used for quantitation of drug product strength, if the methods used for content uniformity are also appropriate as assays.

In cases where use of a nonspecific assay is justified, other supporting analytical procedures should be used to achieve overall specificity. For example, where titration is adopted to assay the drug substance for release, the combination of the assay and a suitable test for impurities can be used. A specific procedure should be used when there is evidence of excipient interference with the nonspecific assay.

(d) *Impurities:* Organic and inorganic impurities (degradation products) and residual solvents are included in this category. Refer to the ICH guidances on ''Q3B Impurities in New Drug Products'' and ''Q3C Impurities: Residual Solvents'' for detailed information.

Organic impurities arising from degradation of the new drug substance

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