activity, and ''customer satisfaction'' measures of performance; and the proposer's plan must include documentation, analysis of the results, and must show how the results can be used in improving the resource center.

(7) *Management experience and Plans.* Applicants should specify Plans for proper organization, staffing, and management of the implementation process. Factors that may be considered include: Appropriateness and authority of the governing or managing organization to conduct the proposed activities; qualifications and experience of the project team and its leadership to conduct the proposed activity; soundness of any staffing plans, including recruitment, selection, training, and continuing professional development; and appropriateness of the organizational approach for carrying out the proposed activity.

(8) *Financial plan.* Applicants should show the relevance and cost effectiveness of the financial plan for meeting the objectives of the project; the firmness and level of the applicant's total financial support for the project; and a plan to maintain the program after the cooperative agreement has expired. Factors that may be considered include: Reasonableness of the budget, both in income and expenses; strength of commitment and amount of the proposer's *cost share*; effectiveness of management plans for control of the budget; and appropriateness of matching contributions.

§ 291.5 Proposal selection process.

The proposal evaluation and selection process will consist of three principal phases: Proposal qualification; proposal review and selection of finalists; and award determination.

(a) *Proposal qualification.* All proposals will be reviewed by NIST to assure compliance with the proposal content and other basic provisions of this notice. Proposals which satisfy these requirements will be designated qualified proposals; all others will be disqualified at this phase of the evaluation and selection process.

(b) *Proposal review and selection of finalists.* NIST will appoint an evaluation panel composed of NIST and in some cases other federal employees to review and evaluate all qualified proposals in accordance with the evaluation criteria and values set forth in this notice. A site visit may be required to make full evaluation of a proposal. From the qualified proposals, a group of finalists will be numerically ranked and recommended for award based on this review.

(c) *Award determination.* The Director of the NIST, or her/his designee, shall select awardees based on total evaluation scores, geographic distribution, and the availability of funds. All three factors will be considered in making an award. Upon the final award decision, a notification will be made to each of the proposing organizations.

§ 291.6 Additional requirements; federal policies and procedures.

Recipients and subrecipients are subject to all Federal laws and Federal and Department of Commerce policies, regulations, and procedures applicable to Federal financial assistance awards.

[FR Doc. 95–1313 Filed 1–19–95; 8:45 am]

BILLING CODE 3510–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 90N–0376]

RIN 0905–AA73

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Amendment of Certain Requirements for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising certain requirements of the current good manufacturing practice (CGMP) regulations for finished human and veterinary pharmaceuticals. The changes include clarifying the degree of discretion provided to manufacturers to determine whether separate or defined areas of production and storage are necessary, clarifying the standard used to determine the degree of scrutiny necessary to check the accuracy of the input to and output from computer systems, exempting investigational new drug products from bearing an expiration date, permitting the use of a representative sampling plan for the examination of reserve samples, and clarifying the manufacturer's responsibilities regarding batch records during the annual evaluation of drug product quality standards. These revisions will reduce regulatory burdens.

EFFECTIVE DATE: February 21, 1995.

FOR FURTHER INFORMATION CONTACT:

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William G. Marnane, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville MD 20855, 301–594–0678.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 14, 1981 (46 FR 36332), FDA announced that it was undertaking a review of existing regulations with the goal of minimizing regulatory burdens while maintaining an acceptable level of consumer protection. The public was invited to submit information to assist the agency in deciding the priority of review. FDA invited data that would enable the agency to identify specific existing regulations or groups of regulations perceived to be unnecessarily costly, burdensome, or without public benefit, and on the potential savings to be derived from revising or removing regulations.

In the **Federal Register** of July 2, 1982 (47 FR 29004), FDA announced its review priorities based on comments from 125 individuals and organizations. One area selected for regulatory review was part 211 (21 CFR part 211), the regulations that govern CGMP for finished pharmaceuticals.

This, in turn, led to an internal retrospective review that resulted in recommendations to the agency. As a result of the agency review, in the **Federal Register** of February 12, 1991 (56 FR 5671), FDA issued a proposed rule incorporating the recommendations resulting from the review (hereinafter referred to as the proposed rule). Consideration of these comments and any resulting revisions have been incorporated into this final rule and are discussed in detail below.

The agency's review of CGMP regulations is ongoing and FDA anticipates further revisions based on the agency's experience with the regulations, enforcement efforts, and communications with industry and the general public.

II. The Agency's Retrospective Review

The agency conducted an internal retrospective review (the review) of CGMP regulations to determine if any existing provisions should be changed, modified, or removed. Based on that review, the agency concluded that there was a continuing need for the CGMP regulations to protect public health and safety. FDA's examination of individual CGMP provisions revealed that most were necessary and effective in addressing the underlying issues and concerns. The review did, however, result in recommended changes in particular CGMP regulations. These changes were intended to provide drug manufacturers with more flexibility and discretion in manufacturing drug products while maintaining the manufacturing control necessary to ensure drug product quality. The proposed changes are discussed below.

Section 211.42(c) requires separate or defined areas for a firm's operation to prevent contamination or a mixup of drug products or their ingredients. Although the agency's review found that, in general, this provision did not, with the exception of areas of aseptic processing or penicillin production, require the construction of physical barriers, FDA recognized that the word ''defined'' might be subject to differing interpretations. FDA concluded that amending this provision would clarify that, in most cases, manufacturers may exercise their judgment to determine whether separate or defined areas of production and storage are necessary. The agency is currently evaluating the matter of separate or defined areas of production and storage and may, if necessary, issue further clarification in the future.

Several CGMP regulations require that manufacturers take steps to check the accuracy of equipment used in drug production. For example, § 211.68(b) addresses the accuracy of computerized records and data. A number of comments opposed routine checking of the accuracy of input to or output from a previously validated computer on the basis that it was duplicative, redundant, and expensive. FDA reviewed these comments and concluded that, although automated systems may be less prone to error, such systems are not perfect and need to be monitored. Following its review, however, FDA agreed that the degree of monitoring required for computerized systems would differ from that required for manual operations. FDA concluded that this provision of the CGMP regulations should be revised to clarify that the degree and frequency of input/output verification be based on the complexity and reliability of the computer or related system.

Before its retrospective review of the CGMP regulations, FDA declined to grant investigational drug products an unqualified exemption from all or most of the CGMP requirements. Following the retrospective review, however, FDA concluded that it was not always possible to obtain expiration dates for investigational drug products because relatively little stability data may be available at the beginning of a clinical investigation. FDA concluded that the expiration dating requirement should be eliminated for investigational new drug application (IND) products so long as such products otherwise meet the stability requirements provided in the regulation.

Section 211.170(b) requires that most reserve samples be examined visually at least once a year for evidence of deterioration. Manufacturers must keep reserve samples that are representative of each lot or batch of finished drug product. The reserve sample is to consist of at least twice the quantity necessary for all required tests. Comments responding to the July 14, 1981, notice, as well as other communications subsequently received by the agency, recommended deleting this requirement because of the large cost to firms that produce large numbers of lots (or batches) of a drug product. The comments further asserted that this requirement was redundant given other provisions of the regulations.

FDA declines to eliminate this requirement because suggested alternatives do not provide effective surveillance of all lots of a drug product. The agency believes the yearly inspection is necessary to ensure the quality of the drug product. However, following the retrospective review, FDA concluded that manufacturers could meet their obligations under this regulation in a less burdensome way by conducting an annual visual inspection of reserve samples from a representative number of reserve sample lots. Therefore, FDA is revising the regulation to permit the use of a representative sampling plan for examination of reserve samples.

Section 211.180 provides general requirements for the retention, treatment, and handling of CGMP records and reports. Section 211.180(e) requires the evaluation, at least annually, of the quality standards of each drug to determine the need for changes in drug product specifications. Firms must establish and follow written procedures for these annual evaluations, and § 211.180(e)(1) and (e)(2) requires that several specific items be included in such written procedures. For example, § 211.180(e)(1) requires these written procedures to provide for ''[a] review of every batch, whether approved or rejected, and, where applicable, records associated with the batch.''

Following the retrospective review, FDA concluded that some manufacturers, rather than examining representative batch records for each drug product manufactured during the year, construed this provision to require that every batch record was to be reviewed annually and evaluated according to written procedures. Following the retrospective review, FDA decided to clarify § 211.180(e)(1) on this point.

III. Comments on the Proposed Rule

FDA received several comments on the proposed rule. These comments came from pharmaceutical manufacturers, trade associations, and consumers. In general, the comments supported the agency's efforts to remove, where possible, regulatory requirements that could be eliminated without adversely affecting drug product quality. A section-by-section summary of the comments and the agency's response follow.

A. Design and Construction Features

Confusion about the interpretation of § 211.42(c), which requires separate or defined areas for a firm's operation to prevent contamination or mixup, led to the proposed revision of this provision. The proposed revision was intended to clarify that, in many situations, other control systems may be used in lieu of complete physical separation. The proposal would require separate or defined areas to prevent contamination or mixup ''as necessary.''

1. Comments on proposed § 211.42 generally supported the revision. Three comments, however, recommended that the wording be modified. One comment requested that the revision more explicitly emphasize that the utilization of computer-controlled inventory systems obviates the need for physical separation. Two comments suggested removal of any reference to separate or defined areas.

The agency agrees in part and disagrees in part with these comments. The preamble to the proposed rule noted that § 211.42(c) is intended to ensure that sufficient physical separation exists in manufacturing operations to prevent contamination or mixups, and that the degree of separation is dependent on the type of operation and its proximity to other operations in the plant (56 FR 5671 at

5672). The proposed revision was intended to make it clear that the regulation did not necessarily require a separate room or partitioned area. The agency does not, however, intend to disallow the possibility that, in certain instances, it may be necessary to require physical separation to prevent contamination or mixups and, as discussed above, is continuing to review this matter. Sophisticated computer systems may provide more effective inventory control and help reduce mixups, but certain substances, such as penicillin, may pose such a high risk of contamination that a separate or defined area is necessary to ensure the safety of drug products.

The agency has, therefore, retained the reference to separate or defined areas but has revised the final rule to clarify that other control systems may be used that are capable of preventing contamination and mixups. The agency stated in the preamble to the CGMP regulations published in the **Federal Register** of September 29, 1978 (43 FR 45014 at 45037), and reiterated in the proposed rule (56 FR 5671 at 5672 and 5673), and states again here that this provision is intended to ensure that: ''enough physical separation be employed as is necessary to prevent contamination or mixups. The degree of separation will depend on the type of operation and its proximity to other operations within the plant. The phrase 'separate or defined' is not intended necessarily to mean a separate room or partitioned area, if other controls are adequate to prevent mixups and contamination.''

The agency, on its own initiative, has also revised § 211.42 to clarify that the procedures in paragraphs (c)(1) through (c)(10) of that regulation should be protected from contamination or mixups.

B. Automatic, Mechanical, and Electronic Equipment

Section 211.68(b) deals with controls to be exercised over computer operation, data, and records. The provision requires, in part, that input to and output from a computer system or any related or similar system of formulas or data shall be checked for accuracy. The proposal would add a sentence stating that the degree and frequency of input/output verification from a computer or related system of formulas or other records or data are to be determined by the complexity and reliability of such a computer or related system.

2. Although all comments supported the proposed change to § 211.68(b), three of them would modify the wording. The comments suggested that the revised regulation does not accommodate the accepted use of validated computerized drug production and control systems.

FDA declines to amend the rule as suggested by the comments. The agency believes that the wording in the revised rule adequately encompasses the use of validated computerized drug production and control systems.

3. Two comments questioned the need for human verification of operations that are performed by validated computer systems. Both listed other regulations that were not the subject of the proposed rule that required more than one person to verify certain manufacturing operations, apparently in an effort to show that additional personnel would be needed to comply with proposed § 211.68.

FDA notes that the revisions to § 211.68 do not impose any specific personnel requirements. The agency, however, is aware that computers are subject to malfunctions; for example, the abrupt loss of data due to a computer ''crash'' can be a disruptive experience and possibly result in the loss of crucial information regarding the manufacturing process. Less dramatic events, such as faulty data entry or programming, can also trigger a chain of events that result in a serious production error and the possible distribution of an adulterated product. Thus, while increasingly sophisticated system safeguards and computerized monitoring of essential equipment and programs help protect data, no automated system exists that can completely substitute for human oversight and supervision.

The proposed rule stated (56 FR 5671 at 5673), and FDA reiterates here, that while the degree of verification is left to the manufacturer's discretion, the exercise of such discretion, under § 211.68, requires the use of routine accuracy checks to provide a high degree of assurance that input to and output from a computer or related system are reliable and accurate.

The agency intends that each manufacturer will exercise reasonable judgment based on a variety of factors, including, but not limited to, the complexity of the computer or related system, in developing a method to prevent inaccurate data input and output.

C. Expiration Dating

Proposed § 211.137(g) would exempt investigational drug products from expiration dating requirements provided appropriate stability studies demonstrate that such products meet appropriate standards or specifications during their use in clinical investigations.

4. All comments supported the proposed revision of § 211.137. Two comments, however, recommended changes to clarify the labeling requirements for new drug products for investigational use that are to be reconstituted at the time of dispensing. One comment suggested language specifying the requirement's application to new drug products for investigational use to avoid confusion with § 211.137(c), which applies to all drug products that are to be reconstituted at the time of dispensing.

The agency agrees with these comments and has revised the rule accordingly.

5. Proposed § 211.137(g) also deals with new drug products for investigational use that are to be reconstituted at the time of dispensing. The proposed regulation stated that labeling of such products would be required to bear expiration ''dating'' for the reconstituted drug product. One comment suggested changing the proposed requirement instead to require the labeling to bear expiration ''information'' for reconstituted drug products.

The requirement that expiration ''information'' be placed in the labeling of a drug product is found at § 211.137(c), and FDA agrees that this requirement should also apply to § 211.137(g). The final rule has been revised accordingly.

6. One comment recommended that the proposed exemption be extended to other clinical supplies not subject to IND requirements that are distributed for limited clinical testing, such as internal testing or evaluation in laboratories or for market research. Examples cited included drugs subject to over-the-counter drug monographs or Drug Efficacy Study Implementation requirements.

The agency does not agree that clinical supplies not subject to IND requirements should be exempt from expiration dating. The revision recognizes that for IND products it is often difficult or impossible to obtain the data upon which expiration dates are based. IND products are, therefore, exempt from expiration dating requirements provided that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations.

D. Reserve Samples

As previously noted, proposed § 211.170(b) would clarify FDA's intent

that this provision requires visual examination of reserve samples from representative sample lots or batches of a drug product once a year for evidence of deterioration unless such examination would affect the integrity of the reserve sample. The representative sample lots or batches would be selected by acceptable statistical procedures.

7. Although most comments agreed with the proposed change, several questioned the value of the annual visual examination requirement given other required procedures and programs such as stability testing, production record reviews, and complaint investigations.

The agency has carefully considered these comments and has concluded that the requirement for annual visual inspection should be retained. A sufficient number of batches may not be examined during the course of fulfilling the other required procedures and programs, or batches examined may not be representative of annual batch production. As a result, these other procedures and programs cannot replace the annual visual examination, which provides both manufacturers and consumers a greater degree of quality assurance.

8. Three comments requested clarification of the terms ''representative'' and ''acceptable statistical procedures.''

The agency does not believe that it is necessary or useful to define these terms. The terms have been used in the CGMP regulations for over a decade without apparent confusion due, in part, to a widespread recognition that the meaning of the term ''representative'' may vary from one product to another as well as with respect to the various manufacturing processes involved in producing a variety of products. In addition, an incomplete definition might fail to encompass the full variety of regulated products and processes, whereas a complete and inclusive definition with regard to currently available products and technology might not easily be adapted to new technology. Similarly, with respect to the term ''acceptable statistical procedures,'' a more detailed definition would not permit adaptation to or evolution with advances in statistical analysis.

9. Another comment suggested that the phrase ''acceptable statistical procedures'' could be interpreted to require FDA approval. The comment suggested that the term be changed to ''appropriate statistical procedures.''

As noted above, the agency does not believe that the suggested change is necessary or useful. The agency emphasizes that the selection of acceptable statistical procedures does not involve prior agency approval. The choice of such procedures should, however, be based on a knowledge of current statistical methodology and include consideration of the application of such methodology to a particular drug product.

E. General Requirements

Section 211.180(e) requires that written records be maintained so that the data contained therein are available at least annually for evaluation of the quality standards for drug products. Proposed § 211.180(e)(1) was intended to correct the misinterpretation that the regulation required the review of every batch record for every drug product produced during the year. The proposed rule revised the language to require at least annually a review of a representative number of batch records.

10. One comment noted that current technology makes it possible to use computer data to evaluate product quality data to detect adverse trends. The comment asserted that such an approach permitted more effective and frequent evaluation of such data.

The agency agrees that technological advances can produce gains in both the accuracy of data evaluation and the speed at which the process can be conducted, and FDA encourages the use of technology that helps safeguard the integrity of the manufacturing process. However, such computerized information must be used as a complement to, and not as a substitute for, human judgment and intervention. Computerized assessments must be monitored by qualified individuals to detect trends that may provide an early indication of changes in drug product specifications or manufacturing or control procedures that merit attention and intervention. Moreover, other factors such as product complaints and recall information may not be included in the computer data.

11. Several comments requested clarification about the types of records subject to the batch review requirement.

The proposed rule was not intended to change the types of records subject to annual review, but instead to allow review of a representative number of batches in lieu of examining all records from every batch. FDA has, therefore, clarified the final rule to require a review of a representative number of batches, whether approved or rejected, and where applicable, records associated with those batches.

The overall intent of § 211.180(e) is to provide manufacturers with reliable procedures for reviewing the quality standards for each drug product. Thus, FDA advises that, although this final rule does not in all cases require an annual review of every batch record, adopting a procedure to check every batch record would clearly be appropriate if, for example, a representative review of batch records showed an adverse trend in quality.

12. One comment advised that some firms may confuse the requirements with regard to the annual review of representative batches with the requirements for batch review prior to the release of a product under § 211.192.

FDA disagrees with the comment. The final rule amends § 211.180(e), which requires that written records be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product. Section 211.192, by contrast, specifically requires a quality control unit to review drug product production and control records to determine compliance with written procedures prior to the release of a drug product batch. In brief, § 211.180(e) involves a retrospective overall evaluation of the adequacy of the quality standards for drug products, while § 211.192 involves a contemporaneous evaluation of a drug batch to determine its conformity, at the time of marketing, with current quality standards.

13. One comment suggested allowing a biennial review to permit trend analysis when three or fewer product batches are produced each year.

FDA disagrees with this comment. The agency believes that a 2-year interval between formal review of batches is inadequate. Potential problems with product quality standards could go undetected and thereby delay recognition of a need to revise specifications or manufacturing or control procedures. If a serious error is not detected for a long period, the resulting product could pose a threat to public health and safety. Moreover, a trend analysis may be performed in situations where only a few batches are produced annually by using batches produced in preceding years.

14. One comment strongly opposed the proposed changes, stating that every batch record must be reviewed to detect ''drift'' or changes in specifications for components, manufacturing processes, or other procedures. The comment asserted that, without reviewing every batch, deleterious changes might be instituted by a firm employee or employees without the full knowledge of their superiors, particularly the firm's research and development group.

The agency does not believe such additional measures are necessary. This CGMP provision does not stand alone but must be read in context with other CGMP regulations. Those regulations provide a variety of safeguards for different stages and aspects of the drug manufacturing process. It is the CGMP regulations, taken as a whole, that help ensure drug quality. Moreover, the consequences of widespread disclosure of problems with drug product quality resulting from a recall or other ameliorative action are sufficiently severe to provide most firms with a continuing incentive to maintain product quality. The agency has carefully reviewed this issue and believes that the final rule will not reduce drug product quality.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(10) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The amendments to the CGMP regulations are intended to allow drug manufacturers more flexibility and discretion in manufacturing drug products while maintaining those CGMP requirements necessary to ensure drug product quality. Because this may encourage innovation and the development of more efficient manufacturing procedures that should lead to cost savings for drug manufacturers. In addition, the rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 211 is amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: Secs. 201, 501, 502, 505, 506, 507, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 356, 357, 360b, 371, 374).

2. Section 211.42 is amended in the introductory text of paragraph (c) by revising the second sentence to read as follows:

§ 211.42 Design and construction features.

* * * * *

(c) * * * There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures:

* * * * *

3. Section 211.68 is amended by adding a new sentence after the second sentence in paragraph (b) to read as follows:

§ 211.68 Automatic, mechanical, and electronic equipment.

* * * * *

(b) * * * The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system. * * *

4. Section 211.137 is amended by redesignating paragraph (g) as paragraph (h), and by adding new paragraph (g) to read as follows:

§ 211.137 Expiration dating.

* * * * *

(g) New drug products for investigational use are exempt from the requirements of this section, provided that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations. Where new drug products for investigational use are to be reconstituted at the time of dispensing, their labeling shall bear expiration information for the reconstituted drug product.

* * * * *

5. Section 211.170 is amended by revising the fourth sentence in the introductory text of paragraph (b) to read as follows:

§ 211.170 Reserve samples.

* * * * *

(b) * * * Except for those for drug products described in paragraph (b)(2) of this section, reserve samples from representative sample lots or batches selected by acceptable statistical procedures shall be examined visually at least once a year for evidence of deterioration unless visual examination would affect the integrity of the reserve sample. * * *

* * * * *

6. Section 211.180 is amended by revising paragraph (e)(1) to read as follows:

§ 211.180 General requirements.

* * * * *

(e) * * *

(1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch.

* * * * *

Dated: January 11, 1995.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 95–1361 Filed 1–19–95; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 1F4013/R2101; FRL–4930–9]

RIN 2070–AB78

Pesticide Tolerances for Imazethapyr

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes tolerances for the sum of the residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methy1-4-(1-methylethyl)-5-oxo-1*H*-imidazo1-2-yl]-5-ethy1-3-pyridine carboxylic acid, as its ammonium salt and its metabolite, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid, both free and conjugated, in or on