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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Office of the Secretary of Agriculture

7 CFR Part 1

Rules of Practice and Procedure Governing Formal Rulemaking Proceedings Instituted by the Secretary

AGENCY: Office of the Secretary of Agriculture, USDA.

ACTION: Final rule.

SUMMARY: The U.S. Department of Agriculture (USDA) is adopting a final rule to establish rules of practice and procedure governing formal rulemaking proceedings instituted by the Secretary. This final rule applies to rulemakings that are not subject to the rules of practice and procedure for the promulgation of, or an amendment to, marketing orders or research and promotion orders.

DATES: This final rule is effective on December 4, 2017.

FOR FURTHER INFORMATION CONTACT: Rupa Chilukuri, Trial Attorney, Office of the General Counsel, telephone: 202-720-4982, email: Rupa.Chilukuri@ogc.usda.gov.

SUPPLEMENTARY INFORMATION: USDA is issuing this final rule to establish rules of practice and procedure for formal rulemakings to implement certain statutes under the Secretary's purview in a new subpart P under 7 CFR part 1.

The Agricultural Marketing Service has rules of practice and procedure to formulate marketing agreements and marketing orders under 7 CFR part 900. Those rules of practice and procedure are applicable to proceedings under the Agricultural Marketing Agreement Act of 1937, as amended (50 Stat. 246). In addition, rules of practice and procedure also exist for proceedings under the Cotton Research and Promotion Act, as amended (7 U.S.C. 2101–2119), the Egg Research and Consumer Information Act, as amended

(7 U.S.C. 2701–2718), the Pork Promotion, Research, and Consumer Information Act (7 U.S.C. 4801–4819), and the Potato Research and Promotion Act, as amended (7 U.S.C. 2611–2627). Those rules appear under 7 CFR part 1200.

This new subpart largely reflects language in 7 CFR part 900 and 7 CFR part 1200. For purposes of efficiency and modernization, this subpart also includes: A provision requiring that interested persons notify the Administrator of their intent to participate in the hearing, a provision requiring pre-hearing submissions of direct testimony, and a provision allowing the notice of hearing to include alternative procedures.

5 U.S.C. 553, 601, and 804

This final rule establishes agency rules of practice and procedure. Under the Administrative Procedure Act, prior notice and opportunity for comment are not required for the promulgation of agency rules of practice and procedure. 5 U.S.C. 553(b)(3)(A). Only substantive rules require publication 30 days prior to their effective date. 5 U.S.C. 553(d). Therefore, this final rule is effective upon publication in the **Federal Register**.

Furthermore, under 5 U.S.C. 804, this rule is not subject to congressional review under the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121. In addition, because prior notice and opportunity for comment are not required to be provided for this final rule, this rule is exempt from the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

Executive Orders 12866 and 13563

This rule does not meet the definition of a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563. Because this rule is not a significant regulatory action, it has not been reviewed by the Office of Management and Budget.

Executive Order 13771

Additionally, because this rule does not meet the definition of a significant regulatory action it does not trigger the requirements of Executive Order 13771. See OMB's Memorandum titled "Interim Guidance Implementing

Section 2 of the Executive Order of January 30, 2017 titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative proceedings that must be exhausted before parties may file suit in court challenging this rule.

Executive Order 13132

This rule has been reviewed in accordance with the requirements of Executive Order 13132, Federalism. The review reveals that this rule does not contain policies with federalism implications sufficient to warrant federalism consultation under Executive Order 13132.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation would not have substantial and direct effects on tribal governments and would not have significant tribal implications.

Paperwork Reduction Act

This rule contains no information collections or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 1

Administrative practice and procedure.

■ Accordingly, Subpart P is added to Part 1 of Subtitle A of Title 7 of the Code of Federal Regulations to read as follows:

PART 1—ADMINISTRATIVE REGULATIONS

Subpart P—Rules of Practice and Procedure Governing Formal Rulemaking Proceedings Instituted by the Secretary

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Authority: Pub. L. 89–554, 80 Stat. 378, 5 U.S.C. 301.

Subpart P—Rules of Practice and Procedure Governing Formal Rulemaking Proceedings Instituted by the Secretary

§ 1.800 Words in the singular form.

Words in this subpart in the singular form shall be deemed to import the plural, and vice versa, as the context may require.

§ 1.801 Scope and applicability of this subpart.

Except for proceedings covered by 7 CFR part 900, and by 7 CFR part 1200, the rules of practice and procedure in this subpart shall be applicable to all formal rulemaking proceedings.

§ 1.802 Definitions.

As used in this subpart:

Administrator means the Administrator of the Agency administering the statute involved, or any officer or employee of the Agency to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act for the Administrator.

Department means the U.S. Department of Agriculture.

Federal Register means the publication provided for by the Federal Register Act, approved July 26, 1935 (44 U.S.C. 1501–1511), and acts supplementing and amending it.

Hearing means that part of the proceeding that involves the submission of evidence.

Hearing clerk means the Hearing Clerk, U.S. Department of Agriculture, Washington, DC

Judge means any administrative law Judge appointed pursuant to 5 U.S.C. 3105 and assigned to conduct the hearing.

Party means:

(1) Any employee or contractor of the Department acting in an official capacity; or

(2) A person who intends to cross examine a witness at the hearing and has notified the person named in the notice of hearing by specified dates of his or her intent to participate in the hearing as a “party” pursuant to § 1.804.

Proceeding means a proceeding before the Secretary arising under a statute in which the Secretary uses formal rulemaking procedures as set forth in this subpart.

Secretary means the Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act for the Secretary.

Witness means any person who:

(1) Has notified the person named in the notice of hearing by the specified date of his or her intent to participate in the hearing as a witness pursuant to § 1.804; and

(2) Who submits written direct testimony on the proposed regulations pursuant to § 1.807; and

(3) Testifies orally at the hearing.

§ 1.803 Institution of proceedings.

(a) *Filing and contents of the notice of hearing.* A proceeding under this subpart shall be instituted by the Secretary or designee through filing the notice of hearing with the hearing clerk. The notice of hearing shall state:

(1) The legal authority under which the rule is proposed.

(2) The scope and nature of the hearing, including witness instructions for testifying, including the means and timing of the submission of pre-hearing documents, and scheduling, as necessary.

(3) The terms or substance of the proposed rule or a description of the subjects and issues involved.

(4) The time and place of such hearing.

(5) The final date for notification of intent to participate as a party or witness in the hearing pursuant to § 1.804.

(6) The person to whom notification of intent to participate as a party or witness is to be provided pursuant to § 1.804, and the means by which such notifications are to be provided.

(7) Any alternative procedures established pursuant to paragraph (d) of this section.

(b) *Giving notice of hearing.* (1) The Administrator shall give or cause to be given notice of hearing in the following manner:

(i) By publication of the notice of hearing in the **Federal Register**.

(ii) By posting of the notice of hearing to the USDA Web site.

(2) Legal notice of the hearing shall be deemed to be given if notice is given in the manner provided by paragraph (b)(1)(i) of this section.

(c) *Record of notice.* A copy of the notice of hearing published in the **Federal Register** pursuant to paragraph (b)(1)(i) of this section shall be filed with the hearing clerk and submitted to the Judge at the hearing.

(d) *Alternative procedures.* The Administrator may establish alternative procedures for the proceeding that are in addition to or in lieu of one or more procedures in this subpart, provided that the procedures are consistent with 5 U.S.C. 556 and 557. The alternative procedures must be described in the notice of hearing, as required in paragraph (a)(7) of this section.

§ 1.804 Notification by interested persons.

(a) Any person desiring to participate as a party or witness at the hearing shall notify the person named in the notice of hearing, as prescribed in the notice of hearing, on or before the date specified in the notice of hearing. A person may be both a party and a witness.

(b) The notification must clearly state whether the interested person is participating at the hearing as a party, witness, or both.

(c) If a party or witness will be participating with or through a representative or counsel, the notification must so state and provide the name of the representative or counsel.

(d) Persons who fail to comply with this section and any specified instructions in the notice of hearing shall be deemed to have waived their right to participate in the hearing. Failure to comply with this section shall result in the exclusion of any filed written testimony.

§ 1.805 Docket number.

Each proceeding, immediately following its institution, shall be assigned a docket number by the hearing clerk and thereafter the proceeding may be referred to by such number.

§ 1.806 Judge.

(a) *Assignment.* No Judge who has any pecuniary interest in the outcome of a proceeding shall serve as Judge in such proceeding.

(b) *Power of Judge.* Subject to review by the Secretary, as provided elsewhere in this subpart, the Judge in any proceeding shall have power to:

(1) Rule upon motions and requests;

(2) Change the time and place of hearings, and adjourn the hearing from time to time or from place to place;

(3) Administer oaths and affirmations and take affidavits;

(4) Examine and cross-examine witnesses and receive evidence;

(5) Admit or exclude evidence;

(6) Hear oral argument on facts or law; and

(7) Do all acts and take all measures necessary for the maintenance of order at the hearings and the efficient conduct of the proceeding.

(c) *Who may act in absence of the Judge.* In case of the absence of the Judge or that Judge's inability to act, the powers and duties to be performed by the Judge under this subpart in connection with a proceeding may, without abatement of the proceeding unless otherwise ordered by the Secretary, be assigned to any other Judge.

(d) *Disqualification of Judge.* The Judge may at any time withdraw as Judge in a proceeding if such Judge deems himself or herself to be disqualified. Upon the filing by an interested person in good faith of a timely and sufficient affidavit of personal bias or disqualification of a Judge, the Secretary shall determine the matter as a part of the record and decision in the proceeding, after making such investigation or holding such hearings, or both, as the Secretary may deem appropriate in the circumstances.

§ 1.807 Direct testimony submitted as written documents.

Any person desiring to participate as a witness at the hearing shall submit direct testimony as written documents as prescribed by the following:

(a) Direct testimony by a witness, including accompanying exhibits, must be submitted as specified in the notice of the hearing pursuant to § 1.803. Exhibits constituting part of such direct testimony, referred to in the direct testimony and made a part thereof must be attached to the direct testimony. Direct testimony submitted with exhibits must state the issue(s) to which the exhibit relates; if no such statement is made, the Judge, at the hearing, shall determine the relevance of the exhibit to the issues published in the **Federal Register**.

(b) The direct testimony submitted shall contain:

(1) A concise statement of the witness' interest in the proceeding and his or her position regarding the issues presented. If the direct testimony is presented by a witness who is not a party, the witness shall state the witness' relationship to

the party on behalf of whom the testimony is proffered; and

(2) Facts that are relevant and material.

(c) Copies of all direct testimony, including accompanying exhibits, must be submitted as prescribed by the notice of hearing.

(d) Upon receipt, direct testimony shall be assigned a number and stamped with that number and the docket number.

§ 1.808 Motions and requests.

(a) *General.* (1) Parties shall file all motions and requests with the hearing clerk except that those made during the course of the hearing may be filed with the Judge or may be stated orally and made a part of the transcript.

(2) Except as provided in § 1.816(b), such motions and requests shall be addressed to, and ruled on by, the Judge if made prior to certification of the transcript pursuant to § 1.811 or by the Secretary if made thereafter.

(b) *Certification to Secretary.* The Judge may, in his or her discretion, submit or certify to the Secretary for decision any motion, request, objection, or other question addressed to the Judge.

§ 1.809 Conduct of the hearing.

(a) *Time and place.* The hearing shall be held at the time and place established in the notice of hearing. If the Judge subsequently changes the time or place, the Judge shall file a notice of such changes with the hearing clerk, and the Administrator shall give or cause to be given notice in the **Federal Register** in the same manner as provided in § 1.803. If the change in time or place of hearing is made less than five days prior to the date previously established for the hearing, the Judge, either in addition to, or in lieu of, causing the notice of the change to be given, shall announce the change at the time and place previously established for the hearing.

(b) *Appearances—(1) Right to appear.* Any interested person shall be given an opportunity to appear, as a witness, with or without, authorized counsel or representative, and to be heard with respect to matters relevant and material to the proceeding, provided that such interested person complies with §§ 1.804, 1.807, and any alternative procedures included in the hearing notice pursuant to § 1.803. In addition to compliance with any witness instructions set forth in the notice of hearing, any witness who desires to be heard in person at any hearing shall, before proceeding to testify do so under oath or affirmation.

(2) *Appearance with or through counsel or representative.* (i) A witness may appear with counsel or a representative if the witness identifies the counsel or representative in the notification submitted pursuant to § 1.804.

(ii) The counsel or representative shall, before proceeding with the witness testimony, state for the record the authority to act as such counsel or representative, and the names, addresses, and occupations of such counsel or representative.

(iii) The witness or his or her counsel or representative shall give such other information respecting the witness' appearance as the Judge may request.

(3) *Debarment of counsel or representative.* (i) Whenever, while a proceeding is pending before the Judge, such Judge finds that a person, acting as counsel or representative for any party or witness, is guilty of unethical or unprofessional conduct, the Judge may order that such person be precluded from further acting as counsel or representative in such proceeding.

(ii) Except as provided in paragraph (b)(3)(iii) of this section, an appeal to the Secretary may be taken from any such order, but the proceeding shall not be delayed or suspended pending disposition of the appeal.

(iii) In case the Judge has ordered that a person be precluded from further action as counsel or representative in the proceeding, the Judge within a reasonable time thereafter shall submit to the Secretary a report of the facts and circumstances surrounding such order and shall recommend what action the Secretary should take respecting the appearance of such person as counsel or representative in other proceedings before the Secretary. Thereafter the Secretary may, after notice and an opportunity for hearing, issue such order respecting the appearance of such person as counsel or representative in proceedings before the Secretary as the Secretary finds to be appropriate.

(4) *Failure to appear.* If any interested person, who complied with §§ 1.804, 1.807, fails to appear at the hearing, that person shall be deemed to have waived the right to be heard in the proceeding and such failure to appear shall result in the exclusion of that person's written testimony.

(c) *Order of procedure.* (1) The Judge shall, at the opening of the hearing prior to the taking of testimony, note as part of the record the notice of hearing as published in the **Federal Register**.

(2) Evidence shall then be received with respect to the matters specified in the notice of the hearing in such order as the Judge shall announce.

(d) *Evidence*—(1) *General*. The hearing shall be publicly conducted, and the testimony given at the hearing shall be reported verbatim.

(i) Every witness shall, before proceeding to testify, be sworn or make an affirmation.

(ii) When necessary, in order to prevent undue prolongation of the hearing, the Judge may:

(A) Limit the number of times any witness may testify to the same matter or the amount of corroborative or cumulative evidence.

(B) Limit cross examination of a witness by time, scope, or as appropriate, provided that the Judge announces the time limit at the beginning of the hearing, prior to the taking of testimony.

(iii) The Judge shall exclude from the record evidence which is immaterial, irrelevant, or unduly repetitious, or which is not of the sort upon which responsible persons are accustomed to rely.

(2) *Objections*. If a party objects to the admission or rejection of any evidence or to any other ruling of the Judge during the hearing, such party shall state briefly the grounds of such objection, whereupon an automatic exception will follow if the objection is overruled by the Judge. The ruling of the Judge on any objection shall be a part of the transcript. Only objections made before the Judge may subsequently be relied upon in the proceeding.

(3) Upon proper motion, the Judge may accept direct testimony submitted pursuant to § 1.807 into evidence without a witness reading the direct testimony into evidence. Such direct testimony shall become a part of the record subject to exclusion of irrelevant and immaterial parts thereof. A party shall be deemed to have waived the right to introduce pre-hearing written direct testimony and documents if such party fails to present a witness to introduce those documents. The witness introducing direct testimony and documents shall do so under oath or affirmation and shall:

(i) State his or her name, address and occupation.

(ii) State qualifications for introducing the direct testimony. If an expert, the witness shall briefly state the scientific or technical training which qualifies the witness as an expert.

(iii) Identify the direct testimony and documents previously submitted pursuant to § 1.807 of this subpart.

(iv) Submit to direct and cross examination determined to be necessary and appropriate by the Judge.

(4) *Cross examination*. For purposes of this section, the Administrator's or

his or her representative's interest shall be considered adverse to all parties. The Judge may:

(i) Require the cross-examiner to outline the intended scope of the cross examination, which shall generally be limited to the scope of the direct testimony.

(ii) Prohibit parties from cross-examining witnesses unless the Judge has determined that the cross-examiner has an adverse interest on the facts at issue to the party or witness.

(iii) Limit the number of times any party or parties having a common interest may cross-examine an adverse witness on the same matter.

(5) *Proof and authentication of official records or documents*. An official record or document, when admissible for any purpose, shall be admissible as evidence without the presence of the person who made or prepared the same. The Judge shall exercise discretion in determining whether an official publication of such record or document shall be necessary, or whether a copy would be permissible. If permissible such a copy shall be attested to by the person having legal custody of it, and accompanied by a certificate that such person has the custody.

(6) *Exhibits*. (i) All written statements, documents, charts, tabulations, or data offered into evidence at the hearing shall, after identification by the witness or his or her counsel or representative and upon satisfactory showing of authenticity, relevancy, and materiality, be numbered as exhibits and received in evidence and made a part of the record.

(ii) Such exhibits shall be submitted in quadruplicate and in documentary form.

(7) *Official notice*. (i) Subject to paragraph (d)(7)(ii) of this section, official notice at the hearing may be taken of such matters as are judicially noticed by the courts of the United States and of any other matter of technical, scientific, or commercial fact of established character.

(ii) Interested persons shall be given an adequate period of time, at the hearing or subsequent to it, of matters so noticed and shall be given adequate opportunity to show that such facts are inaccurate or are erroneously noticed.

(8) *Offer of proof*. (i) Whenever evidence is excluded from the record, the party offering such evidence may make an offer of proof, which shall be included in the transcript.

(ii) The offer of proof shall consist of a brief statement describing the evidence to be offered. If the evidence consists of a brief oral statement, it shall be inserted into the transcript; if the evidence consists of an exhibit(s), it

shall be inserted into the record for the purpose of an offer of proof. In such event, it shall be considered a part of the record if the Secretary determines that the Judge's ruling in excluding the evidence was erroneous.

(iii) The Judge shall not allow the insertion of such evidence in toto if the taking of such evidence will consume a considerable length of time at the hearing. In such event, if the Secretary determines that the Judge erred in excluding the evidence, and that such error was substantial, the hearing may be reopened to permit the taking of such evidence.

§ 1.810 Oral and written arguments.

(a) *Oral argument before the Judge*. Oral argument before the Judge shall be in the discretion of the Judge. Such argument, when permitted, may be limited by the Judge to any extent that the Judge finds necessary for the expeditious disposition of the proceeding and shall be made part of the transcript.

(b) *Briefs, proposed findings, and conclusions*. (1) The Judge shall announce at the hearing a reasonable period of time within which interested persons may file with the hearing clerk proposed findings and conclusions, and written arguments or briefs, based upon the evidence received at the hearing, citing, where practicable, the page or pages of the transcript of the testimony where such evidence appears.

(2) Factual material other than that adduced at the hearing or subject to official notice shall not be alluded to therein, and, in any case, shall not be considered in the formulation of the rule.

(3) If the person filing a brief desires the Secretary to consider any objection made by such person to a ruling of the Judge, as provided in § 1.809(d), that person shall include in the brief a concise statement concerning each such objection, referring, where practicable, to the pertinent pages of the transcript.

§ 1.811 Certification of the transcript.

(a) The Judge shall notify the hearing clerk of the close of a hearing and of the time for filing transcript corrections, written arguments, briefs, proposed findings, and proposed conclusions.

(b)(1) After the hearing, the Administrator, shall transmit to the hearing clerk an original and three copies of the transcript of the testimony and the original and all copies of the exhibits not already on file with the hearing clerk.

(2) The Judge shall attach to the original transcript of the testimony a certificate stating that, to the best of the

Judge's knowledge and belief, the transcript is a true transcript of the testimony given at the hearing, except in such particulars as the Judge shall specify, and that the exhibits transmitted are all the exhibits as introduced at the hearing with such exceptions as the Judge shall specify. A copy of such certificate shall be attached to each of the copies of the transcript of testimony.

(3) In accordance with such certificate the hearing clerk shall note upon the official record copy, and cause to be noted on other copies of the transcript, each correction detailed therein by adding or crossing out (but without obscuring the text as originally transcribed) at the appropriate place any words necessary to make the same conform to the correct meaning, as certified by the Judge.

(4) The hearing clerk shall obtain and file certifications to the effect that such corrections have been effectuated in copies other than the official record copy.

§ 1.812 Copies of the transcript.

(a) During the period in which the proceeding has an active status in the Department, a copy of the transcript and exhibits shall be kept on file with the hearing clerk where it shall be available for examination during official hours of business. Thereafter the transcript and exhibits shall be made available by the hearing clerk for examination during official hours of business after prior request and reasonable notice to the hearing clerk.

(b) A copy of the transcripts of the hearing shall be made available to any person at actual cost of duplication.

§ 1.813 Administrator's recommended decision.

(a) *Preparation.* As soon as practicable following the termination of the period allowed for the filing of written arguments or briefs and proposed findings and conclusions the Administrator shall file with the hearing clerk a recommended decision.

(b) *Contents.* The Administrator's recommended decision shall include:

(1) A preliminary statement containing a description of the history of the proceedings, a brief explanation of the material issues of fact, law and proposed findings and conclusions about such issues, including the reasons or basis for such proposed findings.

(2) A ruling upon proposed findings or conclusions submitted by interested persons.

(3) An appropriate proposed rule effectuating the Administrator's recommendations.

(c) *Exceptions to recommended decision.* (1) Immediately following the filing of the recommended decision, the Administrator shall give notice thereof and opportunity to file exceptions thereto by publication in the **Federal Register**.

(2) Within the period of time specified in such notice, any interested person may file with the hearing clerk exceptions to the Administrator's proposed rule and a brief in support of such exceptions.

(3) Such exceptions shall be in writing, shall refer, where practicable, to the related pages of the transcript, and may suggest appropriate changes in the proposed rule.

(d) *Omission of recommended decision.* The procedure provided in this section may be omitted only if the Secretary finds on the basis of the record that due and timely execution of the Secretary's functions imperatively and unavoidably requires such omission.

§ 1.814 Submission to Secretary.

(a) Upon the expiration of the period allowed for filing exceptions or upon request of the Secretary, the hearing clerk shall transmit to the Secretary the record of the proceeding.

(b) Such record shall include:

(1) All motions and requests filed with the hearing clerk and rulings thereon.

(2) The certified transcript.

(3) Any proposed findings or conclusions or written arguments or briefs that may have been filed.

(4) The Administrator's recommended decision, if any.

(5) Filed exceptions.

§ 1.815 Decision by the Secretary.

After due consideration of the record, the Secretary shall render a decision. Such decision shall become a part of the record and shall include:

(a) A statement of findings and conclusions, including the reasons or basis for such findings, upon all the material issues of fact or law presented on the record.

(b) A ruling upon proposed findings and proposed conclusions not previously ruled upon in the record.

(c) A ruling upon exceptions filed by interested persons.

(d) Either a denial of the proposal to issue a rule, or, if the findings upon the record so warrant, a rule, the provisions of which shall be set forth and such rule shall be complete.

§ 1.816 Filing, extension of time, effective date of filing, and computation of time.

(a) *Number of copies.* Except as provided otherwise, all documents or

papers required or authorized by the foregoing provisions hereof to be filed with the hearing clerk shall be filed in quadruplicate. Any documents or papers so required or authorized to be filed with the hearing clerk shall be filed with the Judge during the course of an oral hearing.

(b) *Extension of time.* (1) The time for filing of any document or paper required or authorized by the foregoing provisions to be filed may be extended by the Judge (before the record is so certified by the Judge) or by the Administrator (after the record is so certified by the Judge but before it is transmitted to the Secretary), or by the Secretary (after the record is transmitted to the secretary) upon request filed, and if, in the judgment of the Judge, Administrator, or the Secretary, as the case may be, there is good reason for the extension.

(2) All rulings made pursuant to this paragraph shall be filed with the hearing clerk.

(c) *Effective date of filing.* Any document or paper required or authorized in this subpart to be filed shall be deemed to be filed at the time it is received by the Hearing Clerk.

(d) *Computation of time.* (1) Each day, including Saturdays, Sundays, and legal public holidays, shall be included in computing the time allowed for filing any document or paper.

(2) That when the time for filing a document or paper expires on a Saturday, Sunday, or legal public holiday, the time allowed for filing the document or paper shall be extended to include the following business day.

§ 1.817 Ex parte communications.

(a) For the purposes of this section, ex parte communication means any oral or written communication not on the public record with respect to which reasonable prior notice to all interested parties is not given, but which shall not include requests for status reports (including requests on procedural matters) on a proceeding.

(b) At no stage of the proceeding following the issuance of a notice of hearing and prior to the issuance of the Secretary's decision thereon shall an employee of the Department who is or may reasonably be expected to be involved in the decision process of the proceeding discuss ex parte the merits of the proceeding with any person having an interest in the proceeding or with any representative of such person. This prohibition does not include communications about:

(1) Procedural matters and status reports.

(2) The merits of the proceeding if all parties known to be interested in the proceeding have been given notice and an opportunity to participate. A memorandum of any such discussion shall be included in the record of the proceeding.

(c) No interested person outside the Department shall make or knowingly cause to be made to an employee of the Department who is or may reasonably be expected to be involved in the decisional process of the proceeding, an ex parte communication relevant to the merits of the proceeding except as provided in paragraph (a) of this section.

(d) If an employee of the Department who is or may reasonably be expected to be involved in the decisional process of the proceeding receives or makes or knowingly causes to be made a communication prohibited by this section, the Department shall place on the public record of the proceeding:

- (1) All such written communications;
- (2) Memoranda stating the substance of all such oral communications; and
- (3) All written responses, and memoranda, stating the substance of all oral responses thereto.

(e) Upon receipt of a communication knowingly made or knowingly caused to be made by a party in violation of this section, the Department may, to the extent consistent with the interest of justice and the policy of the underlying statute, require the party to show cause why his claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation.

(f) This section does not constitute authority to withhold information from Congress.

§ 1.818 Additional documents to be filed with hearing clerk.

In addition to the documents or papers required or authorized by the foregoing provisions of this subpart to be filed with the hearing clerk, the hearing clerk shall receive for filing and shall have custody of all papers, reports, records, orders, and other documents which relate to the administration of any order and which the Secretary is required to issue or to approve.

§ 1.819 Hearing before Secretary.

(a) The Secretary may act in the place and stead of a Judge in any proceeding herein. When the Secretary so acts, the hearing clerk shall transmit the record to the Secretary at the expiration of the period provided for the filing of proposed findings of fact, conclusions, and orders, and the Secretary shall then,

after due consideration of the record, issue the final decision in the proceeding.

(b) The Secretary may issue a tentative decision in which event the parties shall be afforded an opportunity to file exceptions before the issuance of the final decision.

Stephen Alexander Vaden,

Principal Deputy General Counsel, Office of the General Counsel.

[FR Doc. 2017-23877 Filed 11-2-17; 8:45 am]

BILLING CODE 3410-90-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-472]

Schedules of Controlled Substances: Temporary Placement of FUB-AMB Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic cannabinoid, methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate [FUB-AMB, MMB-FUBINACA, AMB-FUBINACA], and its optical, positional, and geometric isomers, salts, and salts of isomers into schedule I. This action is based on a finding by the Administrator that the placement of this synthetic cannabinoid into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, FUB-AMB.

DATES: This temporary scheduling order is effective November 3, 2017, until November 4, 2019. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement

Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling¹ for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.² The Acting Administrator transmitted notice of his intent to place FUB-AMB into schedule I on a temporary basis to the Assistant Secretary for Health by letter dated May 19, 2017. The Assistant Secretary responded to this notice by letter dated June 9, 2017, and advised that based on a review by the Food and Drug Administration (FDA), there were no active investigational new drug applications or approved new drug

¹ Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this notification adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.

² As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the Department of Health and Human Service (HHS) in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.