SMALL BUSINESS ADMINISTRATION

13 CFR Part 134

RIN 3245–AG87

Rules of Practice for Protests and Appeals Regarding Eligibility for Inclusion in the U.S. Department of Veterans Affairs Center for Verification and Evaluation Database

AGENCY: U.S. Small Business Administration.

ACTION: Final rule.

SUMMARY: The U.S. Small Business Administration (SBA) is amending the rules of practice of its Office of Hearings and Appeals (OHA) to implement procedures for protests of eligibility for inclusion in the Department of Veterans Affairs (VA) Center for Verification and Evaluation (CVE) database, and procedures for appeals of denials and cancellations of inclusion in the CVE database. These amendments are issued in accordance with sections 1832 and 1833 of the National Defense Authorization Act for Fiscal Year 2017 (NDAA 2017).

DATES: This rule is effective on October 1, 2018.

FOR FURTHER INFORMATION CONTACT: Kenneth M. Hyde, Administrative Judge, (202) 401–8200.

SUPPLEMENTARY INFORMATION: Sections 1832 and 1833 of the National Defense Authorization Act for Fiscal Year 2017, Public Law 114–328, 130 Stat. 2000 (Dec. 23, 2016) authorize the SBA's OHA to determine protests and appeals related to inclusion in the CVE database. In order to implement these sections, this rule amends OHA's jurisdiction in subparts A and B of 13 CFR part 134 to include protests of eligibility for inclusion in the CVE database, and appeals of denials and cancellations of inclusion in the CVE database. In addition, this rule creates a new subpart J in 13 CFR part 134 to set detailed rules of practice for protests of eligibility for inclusion in the VA CVE database, and a new subpart K to set detailed rules of practice for appeals of denials and cancellations of verification for inclusion in the VA CVE database.

On September 28, 2017, SBA published in the **Federal Register** (82 FR 45212) a proposed rule to implement sections 1832 and 1833 of the NDAA 2017 and to amend OHA's jurisdiction and procedures in order to accommodate protests of eligibility for inclusion in the CVE database and appeals of denials and cancellations of inclusion in the CVE database. The proposed rule allowed for a comment period ending on October 30, 2017. During the comment period, SBA received thirteen comments.

Summary of Comments and SBA's Response

A. Subparts A and B

SBA proposed amending § 134.102, which defines OHA's jurisdiction, to add protests of eligibility for inclusion in the CVE database and appeals of denials and cancellations of inclusion in the CVE database as two new types of proceedings over which OHA would have jurisdiction. SBA also proposed adding new paragraphs (8) and (9) to § 134.201(b) to identify the location of the regulations concerning protests of eligibility for inclusion in the CVE database and appeals of denials and cancellations of inclusion in the CVE database. As a result of these new paragraphs, SBA also proposed to redesignate existing § 134.201(b)(8) as § 134.201(b)(10). There were no comments on these specific revisions, and SBA is adopting them exactly as proposed.

SBA received four comments that were generally supportive of transferring the protests and appeals at issue from VA to OHA for adjudication. In addition, four other comments described the commenters' views and experiences with existing processes. SBA is unable to respond to these comments as they did not address the proposed regulations at issue here.

B. Subpart J

SBA proposed to add a new subpart J, consisting of §§ 134.1001 through 134.1013, to establish the rules of practice before OHA for protests of eligibility for inclusion in the CVE database (CVE Protests). The new rules of practice for CVE Protests mirror SBA's existing rules for protests of service-disabled veteran-owned small businesses, found in 13 CFR part 125, subpart D.

SBA received no comments regarding the proposed new §§ 134.1001 (Scope of rules), 134.1002 (Who may file a CVE Protest?), 134.1004 (Commencement of CVE Protests), 134.1005 (Contents of the CVE Protest), 134.1006 (Service and filing requirements), 134.1008 (Discovery), 134.1009 (Oral hearings), 134.1010 (Standard of review and burden of proof), 134.1011 (Weight of evidence), 134.1012 (The record), and 134.1013 (Request for reconsideration). Except for § 134.1001, which SBA is amending to delete a duplicative sentence, SBA is adopting these provisions exactly as proposed. As discussed below, SBA received comments on proposed §§ 134.1003 and 134.1007.

The penultimate sentence in proposed § 134.1001(c) stated that ''All protests relating to a concern's status as a SDVO SBC for a non-VA procurement are subject to part 125 of this chapter and must be filed in accordance with that part.'' This sentence is duplicative with language in § 134.1001(d), so SBA is amending § 134.1001(c) to remove the sentence. No other changes were made to § 134.1001.

Proposed § 134.1003 outlined the grounds for filing a CVE Protest. Proposed paragraph (c) required the Judge to determine a protested concern's eligibility for inclusion in the CVE database as of the date the protest was filed. SBA received one comment on paragraph (c). The commenter states that proposed § 134.1003(c) is inconsistent with VA Acquisition Regulation (VAAR) clause 852.219–10(b), VA Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside, which indicates that offers received that are not from service-disabled veteran-owned small businesses will not be considered and that award must be made to a service-disabled veteran-owned small business. The commenter adds that this clause has been interpreted by CVE to mean that eligibility is determined both at the time a bid or initial proposal containing price has been submitted, and at time of award. In addition, the commenter observes that 13 CFR 125.18(a) requires service-disabled veteran-owned small business concerns to self-certify their status at time of initial offer, including price, and also that similar language is found at Federal Acquisition Regulation 19.1403(b). The commenter further maintains that a concern's status may change between the date of proposal submission and the date of award. The commenter urges SBA to revise proposed § 134.1003(c) so that eligibility is determined as of the date the initial proposal with pricing, or bid, was submitted.

In response, SBA agrees with the commenter that, if the CVE Protest pertains to a procurement, SBA should examine eligibility at two separate points: (1) As of the date the concern submits its bid or initial offer, which includes price; and (2) as of the date the CVE Protest was filed. Such an approach would restrict concerns that became ineligible after their initial bid or proposal from being awarded contracts. However, SBA notes that, under 38 U.S.C. 8127(f)(8)(B), the Secretary of the VA or his/her designee may initiate a CVE Protest that does not involve a procurement. In this situation,

there would be no bid or proposal, so eligibility can be assessed only as of the date of the CVE Protest. Accordingly, the commenter's recommendation is accepted in part, and SBA is revising the language of § 134.1003(c).

Section 134.1007 proposed to establish the process for CVE Protests as follows: Paragraph (a) required OHA to issue a notice and order if the protest is found to be timely, specific, and based on protestable allegations; paragraph (b) required dismissal of a protest if the Judge determines the protest to be premature, untimely, nonspecific, or based on non-protestable allegations; paragraph (c) required the Director of the CVE (D/CVE) to send the case file to OHA by the deadline specified in the notice and order; paragraph (d) described the process for requesting a protective order; paragraph (e) allowed for supplemental arguments after a protester reviews the CVE case file; paragraph (f) allowed for a response to a protest within 15 days of the date the protest was filed; and paragraph (g) required the Judge to base the decision on the case file and information provided by the parties or information requested by the Judge. The proposed rule also authorized the Judge to investigate issues beyond those raised by the parties. Paragraph (h) proposed to allow a contracting officer to award the contract after a protest is filed but before a decision is reached if the contracting officer determines the public interest will be protected and notifies the Judge of his/her decision; paragraph (i) required OHA to serve all parties with the decision, which would be a final agency decision; paragraph (j) set out the effects of the decision upon the protested concern and the contract at issue.

SBA received no public comments on § 134.1007. However, VA recommended that § 134.1007(j)(2) be amended to be consistent with VA's existing regulation in VAAR 819.307(h). Specifically, the proposed § 134.1007(j)(2) stated that ''A contracting officer shall not award a contract to a protested concern that the Judge has determined is not eligible for inclusion in the CVE database. If the contracting officer has already made an award under paragraph (h), the contracting officer shall either terminate the contract or not exercise the next option.'' VA recommended that the provision instead read: ''A contracting officer shall not award a contract to a protested concern that the Judge has determined is not eligible for inclusion in the CVE database. If the contract has already been awarded, then the awarded contract shall be deemed void ab initio and the contracting officer shall rescind the contract and award the contract to the next [eligible concern] in line for the award.'' SBA believes this change is minor because, under the proposed § 134.1007(h), a contracting officer normally would not have made an award by the time a CVE Protest is decided. Furthermore, VA's suggestion removes a potential inconsistency between the two agencies' regulations. Therefore, SBA is adopting the comment and revising § 134.1007(j)(2) to mirror VA's existing regulation at VAAR 819.307(h).

C. Subpart K

SBA proposed to add a new subpart K, consisting of §§ 134.1101 through 134.1112, promulgating the rules of practice before OHA for appeals of denials and cancellations of verification for inclusion in the VA CVE database (CVE Appeals). SBA received no comments regarding the proposed §§ 134.1101 (Scope of rules), 134.1102 (Who may file a CVE Appeal?), 134.1103 (Grounds for filing a CVE Appeal), 134.1105 (The appeal petition), 134.1106 (Service and filing requirements), 134.1107 (Transmission of the case file), 134.1108 (Response to an appeal petition), 134.1109 (Discovery and oral hearings), and 134.1111 (Standard of review and burden of proof). Therefore, SBA is adopting these provisions exactly as proposed. SBA, however, received comments on proposed § 134.1104 (Commencement of CVE Appeals), § 134.1110 (New evidence), and § 134.1112 (The decision).

Proposed § 134.1104 required CVE Appeals to be filed within 10 business days of being notified that the CVE status has been denied or cancelled. Paragraph (b) proposed to adopt the rules for counting days found at § 134.202(d). Paragraph (c) proposed to require OHA to dismiss any untimely appeal.

SBA received three comments on § 134.1104. All three commenters stated that 10 business days to file a CVE Appeal is too short a timeframe. The commenters contend that preparing the appeals requires gathering a significant amount of documents and developing responses to legal issues. The three commenters recommend a 30 calendar day time period for filing a CVE Appeal.

In response, SBA notes that CVE Appeals will be based on the documentation provided to the VA by the business concern. In turn, VA will be responsible for producing this record to OHA. The commenters' concern that a 10 business day timeline is too short because documents will need to be provided on appeal is thus unwarranted. On appeal, a business concern will not be required to compile the record or produce new documents. SBA is thus adopting § 134.1104 exactly as proposed.

Proposed § 134.1110 prohibited the introduction of new evidence in CVE Appeals, unless good cause is shown. SBA received one comment on this section. The commenter stated that the section should be revised to allow a denied concern to resubmit its application, thus restarting the verification process, if new evidence is available.

SBA responds that under proposed § 134.1112(c), ''Decisions under this part will be based primarily on the evidence in the CVE case file, arguments made on appeal, and any response(s) thereto.'' Thus, SBA does not anticipate that new evidence will typically be necessary to decide a CVE Appeal. Nevertheless, a party that can establish good cause for the introduction of new evidence may do so under proposed § 134.1110. SBA believes that allowing new evidence to be introduced and allowing the Judge to consider the evidence will negate the necessity of restarting the verification process. The limitations on the introduction of new evidence in proposed § 134.1110 are consistent with OHA's restrictions on the use of new evidence in other types of proceedings. *See* 13 CFR 134.308 (limitations on the use of new evidence in size appeals). Therefore, SBA will not alter § 134.1110 and is adopting it exactly as proposed.

Under proposed § 134.1112(a) the Judge would decide a CVE Appeal, if practicable, within 60 calendar days after the close of record. SBA received one comment on this section. The commenter argues the decisions should be rendered within 30 calendar days, because 60 days is too long to wait for a decision. The commenter further argues the appeal should be automatically granted if OHA does not issue the decision by the deadline.

In response, SBA notes that CVE Appeals under subpart K are not tied to a particular procurement. These appeals are of denials and cancellations of verification for inclusion in the VA CVE database, so there is no pending procurement at stake. Further, the 60 day timeframe is similar to that used by OHA in deciding 8(a) eligibility cases (13 CFR 134.409). As a result, SBA does not agree that a more expedited timeframe is warranted. In addition, SBA does not agree that it would be appropriate to automatically reinstate a concern in the CVE database due to a delay in issuing a decision, because such an approach might enable

ineligible concerns to bid on VA contracts. SBA will not alter § 134.1112(a) and is adopting it exactly as proposed.

Proposed § 134.1112(g) allowed any party that has appeared in the proceeding, or the Secretary of VA or his or her designee, to file a petition for reconsideration. As proposed, the petition must be filed within twenty (20) calendar days after service of the written decision, upon a clear showing of an error of fact or law material to the decision. The Judge also may reconsider a decision on his or her own initiative.

SBA received one comment on this paragraph. The commenter states that 20 calendar days allowed for filing a petition for reconsideration is too long, and suggests changing it to 10 calendar days.

SBA responds that 20 calendar days is the standard for other OHA proceedings, as set forth under OHA's rules in 13 CFR 134.227(c). Thus, SBA will not alter its timelines and adopts § 134.1112(g) exactly as proposed. There were no comments on the remaining paragraphs of § 134.1112 and SBA is adopting them exactly as proposed.

Compliance With Executive Orders 12866, 12988, 13132, 13771, the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612) Executive Order 12866

OMB has determined that this final rule does not constitute a ''significant regulatory action'' under Executive Order 12866. This final rule is also not a major rule under the Congressional Review Act, 5 U.S.C. 800. This final rule amends the rules of practice for the SBA's OHA in order to implement procedures for protests of eligibility for inclusion in the CVE database, and appeals of denials and cancellations of inclusion in the CVE database. As such, the rule has no effect on the amount or dollar value of any Federal contract requirements or of any financial assistance provided through SBA or VA. Therefore, the rule is not likely to have an annual economic effect of $100 million or more, result in a major increase in costs or prices, or have a significant adverse effect on competition or the United States economy. In addition, this rule does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency, materially alter the budgetary impact of entitlements, grants, user fees, loan programs or the rights and obligations of such recipients, nor raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Executive Order 12988

This action meets applicable standards set forth in section 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

This final rule does not have Federalism implications as defined in Executive Order 13132. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Executive Order. As such it does not warrant the preparation of a Federalism Assessment.

Executive Order 13771

This final rule is not an Executive Order 13771 regulatory action because this final rule is not significant under Executive Order 12866.

Paperwork Reduction Act

The SBA has determined that this final rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, as amended (RFA), 5 U.S.C. 601–612, requires Federal agencies to consider the effect of their actions on small entities, small non-profit businesses, and small local governments. Pursuant to the RFA, when an agency issues a final rule, the agency must prepare a final regulatory flexibility analysis (FRFA). The FRFA describes whether the impact of the rule will have a significant economic impact on a substantial number of small entities, which includes small businesses, small not-for-profit organizations, and small governmental jurisdictions. However, Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an FRFA, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

This final rule revises the regulations governing cases before SBA's Office of Hearings and Appeals, SBA's administrative tribunal. These regulations are procedural by nature. Specifically, this final rule establishes rules of practice for the SBA's OHA in order to implement protests of eligibility for inclusion in the CVE database and appeals of denials and cancellations of inclusion in the CVE database, new types of administrative litigation mandated by sections 1832 and 1833 of the National Defense Authorization Act for Fiscal Year 2017. This legislation provides a new statutory right to challenge eligibility for inclusion in the CVE database, as well as denials and cancellation of inclusion in the CVE database. This final rule merely provides the rules of practice at OHA for the orderly hearing and disposition of protests of CVE database inclusion and appeals of denials and cancellations of CVE database inclusion. At the proposed stage, SBA did not anticipate that this final rule would have a significant economic impact on any small businesses (the only small entities that would be affected by this rule); we did request comments from any small business on how and to what degree this final rule would affect it economically. No comments were received regarding RFA issues. Therefore, the Administrator of SBA certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 13 CFR Part 134

Administrative practice and procedure, Claims, Equal access to justice, Lawyers, Organization and functions (Government agencies).

For the reasons stated in the preamble, SBA amends 13 CFR part 134 as follows:

PART 134—RULES OF PROCEDURE GOVERNING CASES BEFORE THE OFFICE OF HEARINGS AND APPEALS

■ 1. The authority citation for part 134 is revised to read as follows:

Authority: 5 U.S.C. 504; 15 U.S.C. 632, 634(b)(6), 634(i), 637(a), 648(l), 656(i), and 687(c); 38 U.S.C. 8127(f); E.O. 12549, 51 FR 6370, 3 CFR, 1986 Comp., p. 189.

Subpart J issued under 38 U.S.C. 8127(f)(8)(B).

Subpart K issued under 38 U.S.C. 8127(f)(8)(A).

■ 2. Amend § 134.102 by removing the period at the end of paragraph (t) and adding a semicolon in its place and adding paragraphs (u) and (v) to read as follows:

§ 134.102 Jurisdiction of OHA.

* * * * *

(u) Protests of eligibility for inclusion in the Department of Veterans Affairs Center for Verification and Evaluation (CVE) database; and

(v) Appeals of denials and cancellations of inclusion in the CVE database.

■ 3. Amend § 134.201 by:
■ a. Revising the section heading;
■ b. Removing the word ''and'' in paragraph (b)(7);
■ c. Redesignating paragraph (b)(8) as paragraph (b)(10); and
■ d. Adding new paragraphs (b)(8) and (9).

The revision and additions read as follows:

§ 134.201 Scope of the rules in this subpart.

* * * * *

(b) * * *

(8) For protests of eligibility for inclusion in the Center for Verification and Evaluation (CVE) database, in subpart J of this part;

(9) For appeals of denials and cancellations of inclusion in the CVE database, in subpart K of this part; and

* * * * *

■ 4. Add subpart J to read as follows:

Subpart J—Rules of Practice for Protests of Eligibility for Inclusion in the U.S. Department of Veterans Affairs (VA) Center for Verification and Evaluation (CVE) Database (CVE Protests)

Sec.

134.1001 Scope of rules.
134.1002 Who may file a CVE Protest?
134.1003 Grounds for filing a CVE Protest.
134.1004 Commencement of CVE Protests.
134.1005 Contents of the CVE Protest.
134.1006 Service and filing requirements.
134.1007 Processing a CVE Protest.
134.1008 Discovery.
134.1009 Oral hearings.
134.1010 Standard of review and burden of proof.
134.1011 Weight of evidence.
134.1012 The record.
134.1013 Request for reconsideration.

Subpart J—Rules of Practice for Protests of Eligibility for Inclusion in the U.S. Department of Veterans Affairs (VA) Center for Verification and Evaluation (CVE) Database (CVE Protests)

§ 134.1001 Scope of rules.

(a) The rules of practice in this subpart apply to Department of Veterans Affairs' (VA) Center for Verification and Evaluation protests (CVE Protests).

(b) Except where inconsistent with this subpart, the provisions of subparts A and B of this part apply to protests listed in paragraph (a) of this section.

(c) The protest procedures described in this subpart are separate from those governing protests and appeals of a concern's size or status as a Service-Disabled Veteran-Owned Small Business Concern (SDVO SBC) for a non-Department of Veterans Affairs (non-VA) procurement. All protests relating to whether a veteran-owned concern is a ''small'' business for purposes of any Federal program are subject to part 121 of this chapter and must be filed in accordance with that part. If a protester protests both the size of the concern and the concern's eligibility for the CVE database, SBA will process each protest concurrently. SBA does not review issues concerning contract administration.

(d) Protests of a concern's eligibility for a non-VA procurement as a SDVO SBC are governed by 13 CFR part 125, subpart D.

(e) Appeals relating to determinations made by SBA's Director, Office of Government Contracting, regarding SDVO SBC status are governed by subpart E of this part.

(f) Appeals of denials and cancellations of verification for inclusion in the CVE database are governed by subpart K of this part.

§ 134.1002 Who may file a CVE Protest?

A CVE Protest may be filed by:

(a) The Secretary of the VA, or his/her designee; or

(b) In the case of a small business that is awarded a contract for a VA procurement, the contracting officer or an offeror.

§ 134.1003 Grounds for filing a CVE Protest.

(a) *Status.* In cases where the protest is based on service-connected disability, permanent and severe disability, or veteran status, the Judge will only consider a protest that presents specific allegations supporting the contention that the owner(s) cannot provide documentation from the VA, Department of Defense, or the U.S. National Archives and Records Administration to show that they meet the definition of veteran, service-disabled veteran, or service-disabled veteran with a permanent and severe disability.

(b) *Ownership and control.* In cases where the protest is based on ownership and control, the Judge will consider a protest only if the protester presents credible evidence that the concern is not 51% owned and controlled by one or more veterans or service-disabled veterans.

(c) *Date for determining eligibility.* (1) If the CVE Protest pertains to a procurement, the Judge will determine a protested concern's eligibility for inclusion in the CVE database as of the date of bid or initial offer, including price, and as of the date the CVE Protest was filed.

(2) If the CVE Protest does not pertain to a procurement, the Judge will determine a protested concern's eligibility for inclusion in the CVE database as of the date the CVE Protest was filed.

§ 134.1004 Commencement of CVE Protests.

(a) *Timeliness.* (1) The Secretary of the VA, or his/her designee, may file a CVE Protest at any time.

(2) Where the CVE Protest is in connection with a VA procurement:

(i) An offeror must file a CVE Protest within five business days of notification of the apparent awardee's identity.

(ii) A contracting officer may file a CVE Protest at any time during the life of the VA contract.

(3) The rule for counting days is in § 134.202(d).

(4) An untimely protest will be dismissed.

(b) *Filing*—(1) *Private parties.* Interested parties, other than the contracting officer or Secretary of the VA or his/her designee, must deliver their CVE Protests in person, by email, by facsimile, by express delivery service, or by U.S. mail (postmarked within the applicable time period) to the contracting officer.

(2) *Referral to OHA.* The contracting officer must forward to OHA any non-premature CVE Protest received, notwithstanding whether he/she believes it is sufficiently specific or timely. The contracting officer must send all CVE Protests, along with a referral letter, directly to OHA, addressed to Office of Hearings and Appeals, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416, by email at *OHAfilings@sba.gov,* or by facsimile to (202) 205–7059, marked Attn: CVE Protest. The referral letter must include information pertaining to the solicitation that may be necessary for OHA to determine timeliness and standing, including:

(i) The solicitation number;

(ii) The name, address, telephone number, email address, and facsimile number of the contracting officer;

(iii) Whether the contract was sole source or set-aside;

(iv) Whether the protester submitted an offer;

(v) Whether the protested concern was the apparent successful offeror;

(vi) Whether the procurement was conducted using sealed bid or negotiated procedures;

(vii) The bid opening date, if applicable;

(viii) When the protest was submitted to the contracting officer;

(ix) When the protester received notification about the apparent successful offeror, if applicable; and

(x) Whether a contract has been awarded.

(3) *Protests filed by Secretary of the VA.* The Secretary of VA or his/her designee must submit his/her CVE Protest directly to OHA in accordance with the procedures in § 134.204.

(4) *Protests filed by a contracting officer.* The contracting officer must submit his/her CVE Protest directly to OHA in accordance with the procedures in § 134.204. The protest should include in the referral letter the information set forth in paragraph (b)(2) of this section.

§ 134.1005 Contents of the CVE Protest.

(a) CVE Protests must be in writing. There is no required format for a CVE Protest, but it must include the following:

(1) The solicitation or contract number, if applicable;

(2) Specific allegations supported by credible evidence that the concern does not meet the eligibility requirements for inclusion in the CVE database, listed in § 134.1003;

(3) Any other pertinent information the Judge should consider; and

(4) The name, address, telephone number, and email address or facsimile number, if available, and signature of the protester or its attorney.

(b) If the protester intends to seek access to the CVE case file under § 134.205, the protester should include in its protest a request for a protective order. Unless good cause is shown, a protester must request a protective order within five days of filing the protest.

§ 134.1006 Service and filing requirements.

The provisions of § 134.204 apply to the service and filing of all pleadings and other submissions permitted under this subpart.

§ 134.1007 Processing a CVE Protest.

(a) *Notice and order.* If the Judge determines that the protest is timely, sufficiently specific, and based upon protestable allegations, the Judge will issue a notice and order, notifying the protester, the protested concern, the Director, CVE (D/CVE), VA Counsel, and, if applicable, the contracting officer of the date OHA received the protest, and order a due date for responses.

(b) *Dismissal of protest.* If the Judge determines that the protest is premature, untimely, nonspecific, or is based on non-protestable allegations, the Judge will dismiss the protest and will send the contracting officer, D/CVE, and the protester a notice of dismissal, citing the reason(s) for the dismissal. The dismissal is a final agency action.

(c) *Transmission of the case file.* Upon receipt of a notice and order, the D/CVE must deliver to OHA the entire case file relating to the protested concern's inclusion in the CVE database. The notice and order will establish the timetable for transmitting the case file to OHA. The D/CVE must certify and authenticate that the case file, to the best of his/her knowledge, is a true and correct copy of the case file.

(d) *Protective order.* A protester seeking access to the CVE case file must file a timely request for a protective order under § 134.205. Except for good cause shown, a protester must request a protective order within five days of filing the protest. Even after issuance of a protective order, OHA will not disclose income tax returns or privileged information.

(e) *Supplemental allegations.* If, after viewing documents in the CVE case file for the first time under a protective order, a protester wishes to supplement its protest with additional argument, the protester may do so. Any such supplement is due at OHA no later than 15 days from the date the protester receives or reviews the CVE case file.

(f) *Response*—(1) *Timing.* The protested concern, the D/CVE, the contracting officer, and any other interested party may respond to the protest and supplemental protest, if one is filed. The response is due no later than 15 days from the date the protest or supplemental protest was filed with OHA. The record closes the date the final response is due.

(2) *Service.* The respondent must serve its response upon the protester or its counsel and upon each of the persons identified in the certificate of service attached to the notice and order or, if a protective order is issued, in accordance with the terms of the protective order.

(3) *Reply to a response.* No reply to a response will be permitted unless the Judge directs otherwise.

(g) *Basis for decision.* The decision will be based primarily on the case file and information provided by the protester, the protested concern, and any other parties. However, the Judge may investigate issues beyond those raised in the protest and may use other information or make requests for additional information to the protester, the protested concern, or VA.

(h) *Award of contract.* The contracting officer may award a contract during the period between the date he/she receives a protest and the date the Judge issues a decision only if the contracting officer determines that an award must be made to protect the public interest and notifies the Judge in writing of any such determination. Notwithstanding such a determination, the provisions of paragraph (j) of this section shall apply to the procurement in question.

(i) *The decision.* OHA will serve a copy of the written decision on each party, or, if represented by counsel, on its counsel. The decision is considered the final agency action, and it becomes effective upon issuance.

(j) *Effect of decision.* (1) A contracting officer may award a contract to a protested concern after the Judge has determined either that the protested concern is eligible for inclusion in the CVE database or has dismissed all protests against it.

(2) A contracting officer shall not award a contract to a protested concern that the Judge has determined is not eligible for inclusion in the CVE database. If the contract has already been awarded, then the awarded contract shall be deemed void ab initio (invalid from the outset), and the contracting officer shall rescind the contract and award the contract to the next eligible concern in line for the award.

(3) The contracting officer must update the Federal Procurement Data System and other procurement reporting databases to reflect the Judge's decision.

(4) If the Judge finds the protested concern ineligible for inclusion in the CVE database, D/CVE must immediately remove the protested concern from the CVE database.

(5) A concern found to be ineligible may not submit an offer on a future VA procurement until the protested concern reapplies to the Vendor Information Pages Verification Program and has been reentered into the CVE database.

§ 134.1008 Discovery.

Discovery will not be permitted in CVE Protest proceedings.

§ 134.1009 Oral hearings.

Oral hearings will be held in CVE Protest proceedings only upon a finding by the Judge of extraordinary circumstances. If such an oral hearing is ordered, the proceeding shall be conducted in accordance with those rules of subpart B of this part as the Judge deems appropriate.

§ 134.1010 Standard of review and burden of proof.

The protested concern has the burden of proving its eligibility, by a preponderance of the evidence.

§ 134.1011 Weight of evidence.

The Judge will give greater weight to specific, signed, factual evidence than to

general, unsupported allegations or opinions. In the case of refusal or failure to furnish requested information within a required time period, the Judge may assume that disclosure would be contrary to the interests of the party failing to make disclosure.

§ 134.1012 The record.

Where relevant, the provisions of § 134.225 apply. In a protest under this subpart, the contents of the record also include the case file or solicitation submitted to OHA in accordance with § 134.1007.

§ 134.1013 Request for reconsideration.

The decision on a CVE Protest may not be appealed. However:

(a) The Judge may reconsider a CVE Protest decision. Any party that has appeared in the proceeding, or the Secretary of VA or his/her designee, may request reconsideration by filing with OHA and serving a petition for reconsideration on all the parties to the CVE Protest within twenty (20) calendar days after service of the written decision. The request for reconsideration must clearly show an error of fact or law material to the decision. The Judge may also reconsider a decision on his or her own initiative.

(b) If the Judge reverses his or her initial decision on reconsideration, the contracting officer must follow § 134.1007(j) in applying the new decision's results.

■ 5. Add subpart K to read as follows:

Subpart K—Rules of Practice for Appeals of Denials and Cancellations of Verification for Inclusion in the U.S. Department of Veterans Affairs (VA) Center for Verification and Evaluation (CVE) Database (CVE Appeals)

Sec.

134.1101 Scope of rules.
134.1102 Who may file a CVE Appeal?
134.1103 Grounds for filing a CVE Appeal.
134.1104 Commencement of CVE Appeals.
134.1105 The appeal petition.
134.1106 Service and filing requirements.
134.1107 Transmission of the case file.
134.1108 Response to an appeal petition.
134.1109 Discovery and oral hearings.
134.1110 New evidence.
134.1111 Standard of review and burden of proof.
134.1112 The decision.

Subpart K—Rules of Practice for Appeals of Denials and Cancellations of Verification for Inclusion in the U.S. Department of Veterans Affairs (VA) Center for Verification and Evaluation (CVE) Database (CVE Appeals)

§ 134.1101 Scope of rules.

(a) The rules of practice in this subpart apply to appeals of denials and cancellations of verification for inclusion in the U.S. Department of Veterans Affairs Center for Verification and Evaluation Database (CVE Appeals).

(b) Except where inconsistent with this subpart, the provisions of subparts A and B of this part apply to appeals listed in paragraph (a) of this section.

(c) Appeals relating to determinations made by SBA's Director, Office of Government Contracting regarding Service-Disabled Veteran-Owned Small Business Concern (SDVO SBC) status are governed by subpart E of this part.

(d) Protests of a concern's eligibility for inclusion in the VA CVE database are governed by subpart J of this part.

§ 134.1102 Who may file a CVE Appeal?

A concern that has been denied verification of its CVE status or has had its CVE status cancelled may appeal the denial or cancellation to OHA.

§ 134.1103 Grounds for filing a CVE Appeal.

Denials and cancellations of verification of CVE status may be appealed to OHA, so long as the denial or cancellation is not based on the failure to meet any veteran or service-disabled veteran eligibility criteria. Such denials and cancellations are final VA decisions and not subject to appeal to OHA.

§ 134.1104 Commencement of CVE Appeals.

(a) A concern whose application for CVE verification has been denied or whose CVE status has been cancelled must file its appeal within 10 business days of receipt of the denial or cancellation.

(b) The rule for counting days is in § 134.202(d).

(c) OHA will dismiss an untimely appeal.

§ 134.1105 The appeal petition.

(a) *Format.* CVE Appeals must be in writing. There is no required format for an appeal petition; however, it must include the following:

(1) A copy of the denial or cancellation and the date the appellant received it;

(2) A statement of why the cancellation or denial is in error;

(3) Any other pertinent information the Judge should consider; and

(4) The name, address, telephone number, and email address or facsimile number, if available, and signature of the appellant or its attorney.

(b) *Service.* The appellant must serve copies of the entire appeal petition upon the Director, Center for Verification and Evaluation (D/CVE) and VA Counsel at *CVEAppealsService@va.gov.*

(c) *Certificate of service.* The appellant must attach to the appeal petition a signed certificate of service meeting the requirements of § 134.204(d).

(d) *Dismissal.* An appeal petition that does not meet all the requirements of this section may be dismissed by the Judge at his/her own initiative or upon motion of a respondent.

§ 134.1106 Service and filing requirements.

The provisions of § 134.204 apply to the service and filing of all pleadings and other submissions permitted under this subpart.

§ 134.1107 Transmission of the case file.

Once a CVE Appeal is filed, the D/CVE must deliver to OHA the entire case file relating to the denial or cancellation. The Judge will issue a notice and order establishing the timetable for transmitting the case file to OHA. The D/CVE must certify and authenticate that the case file, to the best of his/her knowledge, is a true and correct copy of the case file.

§ 134.1108 Response to an appeal petition.

(a) *Who may respond.* The D/CVE or his/her designee or counsel for VA may respond to the CVE Appeal. The response should present arguments to the issues presented on appeal.

(b) *Time limits.* The notice and order will inform the parties of the filing of the appeal petition, establish the close of record as 15 days after service of the notice and order, and inform the parties that OHA must receive any responses to the appeal petition no later than the close of record.

(c) *Service.* The respondent must serve its response upon the appellant and upon each of the persons identified in the certificate of service attached to the appeal petition pursuant to § 134.1105.

(d) *Reply to a response.* No reply to a response will be permitted unless the Judge directs otherwise.

§ 134.1109 Discovery and oral hearings.

Discovery will not be permitted and oral hearings will not be held.

§ 134.1110 New evidence.

Except for good cause shown, evidence beyond the case file will not be admitted.

§ 134.1111 Standard of review and burden of proof.

The standard of review is whether the D/CVE denial or cancellation was based on clear error of fact or law. The appellant has the burden of proof, by a preponderance of the evidence.

§ 134.1112 The decision.

(a) *Timing.* The Judge shall decide a CVE Appeal, insofar as practicable, within 60 calendar days after close of the record.

(b) *Contents.* Following closure of the record, the Judge will issue a decision containing findings of fact and conclusions of law, reasons for such findings and conclusions, and any relief ordered.

(c) *Basis for decision.* Decisions under this subpart will be based primarily on the evidence in the CVE case file, arguments made on appeal, and any response(s) thereto. However, the Judge, in his/her sole discretion, may consider issues beyond those raised in the pleadings and the denial or cancellation letter.

(d) *Finality.* The decision is the final agency decision and becomes effective upon issuance. Where OHA dismisses an appeal of a D/CVE denial or cancellation, the D/CVE determination remains in effect.

(e) *Service.* OHA will serve a copy of all written decisions on each party, or, if represented by counsel, on its counsel.

(f) *Effect.* If the Judge grants the appeal and finds the appellant eligible for inclusion in the CVE database, the D/CVE must immediately reinstate or include the appellant, as the case may be, in the CVE database.

(g) *Reconsideration.* A decision of the Judge may be reconsidered. Any party that has appeared in the proceeding, or the Secretary of VA or his or her designee, may request reconsideration by filing with OHA and serving a petition for reconsideration on all parties to the CVE Appeal within twenty (20) calendar days after service of the written decision, upon a clear showing of an error of fact or law material to the decision. The Judge also may reconsider a decision on his or her own initiative.

Dated: March 14, 2018.

Linda E. McMahon,

Administrator.

[FR Doc. 2018–06034 Filed 3–29–18; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 556, and 558

[Docket No. FDA–2017–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsorship; Change of a Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July, August, and September 2017. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect the withdrawal of approval of applications, changes of sponsorship of applications, and a change of a sponsor's name and address, and to make technical amendments to improve the accuracy of the regulations.

DATES: This rule is effective March 30, 2018, except for amendatory instructions 3 to 21 CFR 510.600, 9 to 21 CFR 522.300, 10 to 21 CFR 522.540, and 11 to 21 CFR 522.1081, which are effective April 9, 2018.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2017, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2017

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
July 21, 2017	141–450	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	BANAMINE Transdermal (flunixin transdermal solution) Solution.	Cattle	Original approval for the control of pyrexia associated with bovine respiratory disease and the control of pain associated with foot rot in steers, beef heifers, beef cows, beef bulls intended for slaughter, and replacement dairy heifers under 20 months of age.	FOI Summary; EA/FONSI.[1]