outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (*e.g.,* improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, the TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. *Form Number:* CMS–10443 (OMB control number: 0938–1202); *Frequency:* Annual; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 14,871; *Total Annual Responses:* 59,484; *Total Annual Hours:* 19,184. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

Dated: March 15, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–06188 Filed 3–17–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7040–N2]

Health Insurance Marketplace℠, Medicare, Medicaid, and the Children's Health Insurance Program; Cancellation of the March 23, 2016 Advisory Panel on Outreach and Education Meeting

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Cancellation of meeting.

SUMMARY: On February 25, 2016, we published a **Federal Register** notice (81 FR 9483) announcing a new meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel), which was scheduled for Wednesday, March 23, 2016. This notice announces the cancellation of the March 23, 2016 meeting.

FOR FURTHER INFORMATION CONTACT: Abigail Huffman, Designated Federal Official, Office of Communications, CMS, 7500 Security Boulevard, Mail Stop S1–05–06, Baltimore, MD 21244, 410–786–0897, email *Abigail.Huffman1@cms.hhs.gov.* Additional information about the APOE is available on the Internet at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE.html.* Press inquiries are handled through the CMS Press Office at (202) 690–6145.

Dated: March 15, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–06206 Filed 3–17–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3543]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Information in Direct-to-Consumer Television Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 18, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title ''Quantitative Information in Direct-to-Consumer Television Advertisements.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Quantitative Information in Direct-to-Consumer Television Advertisements OMB Control Number 0910—NEW

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

A previous FDA study found that simple quantitative information could be conveyed in direct-to-consumer (DTC) television ads in ways that increased consumer's knowledge about the drug (OMB control number 0910–0663, ''Experimental Study: Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs'') (Ref. 1). However, this research only tested simple information (*e.g.,* one clinical trial, comparison to placebo). Drug information can be much more complicated (*e.g.,* complicated endpoints, multiple study arms). The

following studies are designed to address the question of whether consumers can use more complicated information when assessing prescription drug information in television DTC ads. These studies will build on previous research by: (1) Examining more complicated quantitative information, (2) examining quantitative information for both benefits and risks, and (3) examining how visuals designed to represent efficacy interact with quantitative information.

The objective of this project is to test consumers' understanding of quantitative information about prescription drugs in DTC television ads. In study 1, we plan to examine experimentally the presence and complexity of quantitative benefit and risk information in DTC television ads (table 1). We hypothesize that, replicating past studies, adding simple quantitative information about benefits and risks will lead to increased understanding among consumers. We will test whether adding complex quantitative information results in the same outcomes as simple quantitative information or whether it is too much quantitative information for consumers to process. In study 2, we plan to examine experimentally the presence of quantitative benefit information and how the ad visually represents efficacy (by having no images, images that accurately reflect the improvement in health that could be expected with treatment, or images that overstate the improvement in health that could be expected with treatment (table 2)). We hypothesize that overstated images of improvement will lead consumers to overestimate the drug's efficacy; however, adding a quantitative claim may moderate this effect. To test these hypotheses, we will conduct inferential statistical tests such as analysis of variance (ANOVA). With the sample sizes described in this document, we will have sufficient power to detect small-to medium-sized effects in each study.

All participants will be 60 years of age or older. We will exclude individuals who work in health care or marketing. We selected a sample of participants 60 years and older to increase the likelihood that participants will be interested in the fictitious study drug and therefore motivated to pay attention to the ad during the study. The studies will be conducted with an Internet panel.

In both studies, participants will be randomly assigned to one experimental condition and view the corresponding television ad. The ad will be for a fictitious drug to treat cataracts. The ads will be created and pretested to ensure that consumers perceive different levels of complexity across the ads in study 1 and different levels of image accuracy in study 2. ''Pretests for a Study on Quantitative Information in Direct-to-Consumer Television Advertisements'' was submitted under OMB control number 0910–0695. After viewing the ad twice, participants will complete a questionnaire that assesses consumers' understanding of the drug information, their retention of the information, and their perceptions of the drug. We will also measure covariates such as demographics and numeracy. The questionnaires are available upon request.

TABLE 1—STUDY 1 DESIGN

		Quantitative risk claim		
Quantitative Efficacy Claim	No	No	Yes: General (e.g., Side effects that occur in 10% or less of people who take Drug X include . . .).	Yes: Specific (e.g., Side effects that occur in [6–10%, 1–5%, and less than 1%] of people who take Drug X include . . .).
	Yes: Single outcome (e.g., 52% of people with cataracts improved their vision to 20/40 while taking Drug X compared to 23% without Drug X. [starting at an average baseline of 20/70]).			
	Yes: Multiple outcomes (e.g., 52% of people with cataracts improved their vision to 20/40 while taking Drug X compared to 23% without Drug X. [starting at an average baseline of 20/70]. With Drug X, people could see an average of 85 letters on a 100-letter eye chart, compared to 73 letters without Drug X.).			

TABLE 2—STUDY 2 DESIGN

		Images of improvement		
Quantitative Benefit Claim	No	None	Accurate improvement in health conveyed in images.	Overstated improvement in health conveyed in images.
	Yes (Single outcome)			

In the **Federal Register** of October 13, 2015 (80 FR 61433), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four public comments were received. Two comments called for direct-to-consumer prescription drug advertising to be banned. These comments are outside the scope of the current project. Other comments and their responses follow.

(Comment 1) The first suggestion was that FDA should research the health literacy of approved patient labeling before conducting research on DTC television advertising.

(Response) FDA has a program of research that includes studies on both patient labeling and DTC television advertising (Refs. 1 to 3). This study extends previous research and addresses issues unique to DTC television advertising (*e.g.,* visual representations of efficacy) (Ref. 1). The public is exposed to information about prescription drugs via DTC television advertising and this advertising has a public health impact (Refs. 4 and 5). We disagree that there is a need for approved patient labeling research to be conducted before we study issues unique to DTC television advertising.

(Comment 2) The second suggestion is to consider that because low numeracy individuals are not well-represented in online panels we should implement mechanisms to help validate results across health-literate populations.

(Response) We agree that numeracy may be a crucial variable in this study. We have added a second measure of numeracy (subjective numeracy) and a question on health literacy. We will use these measures to determine whether and how numeracy and health literacy affect our results. If our sample has few individuals with low numeracy, we will note this as a limitation.

(Comment 3) The third suggestion is to use a mixed-method approach, recruiting limited-literacy and low socioeconomic participants for in-person administration of the study and using the Internet panel to gather a broad sample.

(Response) We acknowledge that Internet administration is not perfect and have chosen this method to maximize our budget. We will permit the survey to be taken on a variety of devices. We are excluding phones because the stimuli cannot be fully viewed on a very small screen.

(Comment 4) The fourth suggestion is to use frequencies rather than percentages in the questionnaire.

(Response) A recent review of the literature did not support the view that frequencies are more widely understood than percentages (Ref. 6). This review included two studies conducted in the context of DTC advertising (Refs. 1 and 7). Given these findings, we plan to use percentages in the questionnaire.

(Comment 5) The fifth suggestion is to include a single-item health literacy question to the screener.

(Response) We agree this is an important measure and have added it to the questionnaire.

(Comment 6) This comment requests further rationale for the selection of an older patient population and its impact on the generalizability of study findings to advertisements targeted for younger patient populations.

(Response) Advertising studies often recruit participants who have or who are at risk for the medical condition being advertised to increase interest in the ad and motivation to pay attention to the ad. Older participants are more likely to be at risk for cataracts. In addition, older adults use more prescription drugs and watch more television than younger adults do (Refs. 8 and 9). We will note that the study is not broadly generalizable when we report our findings.

(Comment 7) This comment suggests including a video compatibility test to verify that participants can view the videos and precluding participants from taking the survey using a smartphone device.

(Response) We have added a video compatibility test to the study and will preclude participants from using phones.

(Comment 8) This comment also sought clarification on which stimuli from study 1 will be used in study 2.

(Response) The benefit information in study 2 will be the ''simple'' claim from study 1. Study 2 will not include quantitative risk information. This means that the same ad will be used in the ''simple quantitative benefit claim/no quantitative risk claim'' condition in study 1 and the ''quantitative benefit claim/no images of improvement'' condition in study 2.

(Comment 9) This comment expresses concern that adding complex benefit information in study 1 may cause the content to become unmanageable and suggests adding study arms with more of fewer risks and benefits to assess this.

(Response) Based on this comment and peer reviewer feedback, we will manipulate the complexity of quantitative efficacy claim by adding a second benefit outcome. We have revised the study design tables to reflect this (see tables 1 and 2). The number of risks will be constant but we will manipulate whether and how the frequencies of the risks are presented.

(Comment 10) This comment recommended holding all other aspects outside the variable being tested be held constant across the different treatments.

(Response) We agree with this recommendation. We will create one ad that will be the basis of all the stimuli. We will manipulate this base ad by adding quantitative benefit information, quantitative risk information, and/or images of improvement to create the different experimental conditions, while leaving other factors constant.

(Comment 11) This comment recommends using scales with a neutral midpoint.

(Response) There are advantages and disadvantages to including midpoints in scales (Refs. 10 and 11). Based on responses from similar studies, we have decided to use scales without a midpoint. Instead, we have included a ''don't know'' option for some items that may make participants' responses easier to interpret than a neutral midpoint would.

(Comment 12) This comment noted that without the stimuli it was difficult to tell whether the battery of questions measuring efficacy accuracy was redundant or inapplicable.

(Response) We did not create the stimuli before the public notice so that the public and peer review comments, along with cognitive interviews and pretesting, could inform the creation of the stimuli. Based on peer review, we refined our efficacy claims. We tailored the efficacy accuracy items to reflect the new claims. Some of these questions are designed to measure participants' gist understanding of the drugs' efficacy likelihood and magnitude (Ref. 12). They are not redundant with the questions designed to measure participants' verbatim understanding of the drugs' efficacy likelihood and magnitude. As in previous research, participants in the control condition will not have the information to answer all the accuracy questions (Ref. 1). Instead, this condition serves as a baseline with which to compare the experimental conditions. We added a ''don't know'' option so that these participants can report that they do not know the answer.

(Comment 13) This comment suggested reordering questions so that the perception and intention questions appeared before the questions about efficacy and risk information.

(Response) Based on peer review, we moved the gist questions before the accuracy questions, but we did not move intentions and perceptions before gist and accuracy. We understand the value in getting obtaining intentions and perceptions unbiased by the other

measures. However, we put the gist and accuracy measures first because they are our primary measures; therefore, we want to decrease potential memory decay and ensure the gist and accuracy measures are not biased.

(Comment 14) This comment questioned whether three risk claim accuracy questions in study 1 were redundant with each other and how the stimulus will list frequencies for the risks.

(Response) We updated table 1 to show how risks will be described in each condition. The terms ''least common'' and ''most common'' will not be used in the ads. The questions are not redundant. One question (previously Q17) asks participants to report the frequency for each risk. The other two questions (previously Q20 and Q21) ask participants whether they got the ''gist'' of how common the risks are. If participants are able to understand the gist of the information, then those in the two quantitative risk information conditions should be able to report that the most common risks had a frequency of roughly 10 percent and participants in the specific quantitative risk information condition should be able to report that the least common risks had a frequency of roughly 1 percent. We will cognitively test and pretest these items.

(Comment 15) This comment suggests adding ''don't know'' options to the perceived efficacy and risk questions.

(Response) We added a ''don't know'' option to the questions that ask participants to compare the advertised drug's risks and benefits to other treatments.

FDA estimates the burden of this collection of information as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]—STUDY 1

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sample outgo	15,130				
Number to complete the screener (10%)	1,513	1	1,513	0.05 (3 minutes)	76
Number eligible for survey (70%)	1,059				
Number to complete the survey (85%)	900	1	900	0.33 (20 minutes)	297
Total			2,413		373

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]—STUDY 2

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sample outgo	15,130				
Number to complete the screener (10%)	1,513	1	1,513	0.05 (3 minutes)	75.65
Number eligible for survey (70%)	1,059				
Number to complete the survey (85%)	900	1	900	0.33 (20 minutes)	297
Total			2,413		372.65

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

II. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. O'Donoghue, A.C., H.W. Sullivan, K.J. Aikin, et al., ''Presenting Efficacy Information in Direct-To-Consumer Prescription Drug Advertisements,'' *Patient Education and Counseling,* 95(2):271–280, 2014.
2. Boudewyns, V., A.C. O'Donoghue, B. Kelly, et al., ''Influence of Patient Medication Information Format on Comprehension and Application of Medication Information: A Randomized, Controlled Experiment,'' *Patient Education and Counseling,* 98(12):1592–1599, 2015.
3. Kish-Doto, J., M. Scales, P. Equino-Medina, et al., ''Preferences for Patient Medication Information: What Do Patients Want?'' *Journal of Health Communication,* 19(suppl 2):77–88, 2014.
4. Brownfield, E.D., J.M. Bernhardt, J.L. Phan, et al., ''Direct-To-Consumer Drug Advertisements on Network Television: An Exploration of Quantity, Frequency, and Placement,'' *Journal of Health Communication,* 9(6):491–497, 2004.
5. Niederdeppe, J., S. Byrne, R.J. Avery, et al., ''Direct-To-Consumer Television Advertising Exposure, Diagnosis With High Cholesterol, and Statin Use,'' *Journal of General Internal Medicine,* 28(7):886–893, 2013.
6. Zipkin, D.A., C.A. Umscheid, N.L. Keating, et al., ''Evidence-Based Risk Communication: A Systematic Review,'' *Annals of Internal Medicine,* 161:270–280, 2014.
7. Woloshin, S. and L.M. Schwartz, ''Communicating Data About the Benefits and Harms of Treatment: A Randomized Trial,'' *Annals of Internal Medicine,* 155:87–96, 2011.
8. Zhong, W., H. Maradit-Kremers, J.L. St. Sauver, et al., ''Age and Sex Patterns of Drug Prescribing in a Defined American Population,'' *Mayo Clinic Proceedings,* 88(7):697–707, 2013.
9. Depp, C.A., D.A. Schkade, W.K. Thompson, et al., ''Age, Affective Experience, and Television Use,'' *American Journal of Preventive Medicine,* 39:173–178, 2010.
10. Moors, G., ''Exploring the Effect of a Middle Response Category on Response Style in Attitude Measurement,'' *Quality & Quantity,* 42(6):779–794, 2008.
11. Sturgis, P., C. Roberts, and P. Smith, ''Middle Alternatives Revisited: How the Neither/Nor Response Acts as a Way of Saying ''I Don't Know?'' *Sociological Methods & Research,* 43(1):15–38, 2014.
12. Reyna, V.F., ''How People Make Decisions That Involve Risk: A Dual-Process Approach,'' *Current Directions in Psychological Science,* 13:60–66, 2004.

Dated: March 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06126 Filed 3–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0620]

Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI) #234 entitled ''Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications.'' In order to improve the process for submission and review of chemistry, manufacturing, and controls (CMC) information for animal drugs, the Center for Veterinary Medicine (CVM) has developed a series of questions that focus on the critical scientific and regulatory issues and pharmaceutical attributes essential for ensuring the quality of new animal drug substances and products. Termed Question-based Review (QbR), these questions provide a general framework for original CMC submissions to investigational new animal drug (INAD) files, generic investigational new animal drug (JINAD) files, new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), conditional approval of applications for conditional approval (CNADAs), and veterinary master files (VMFs).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 17, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–0620 for ''Question-Based Review for the Chemistry, Manufacturing, and Controls Technical Section of Animal Drug Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Julie Bailey, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0700, *julie.bailey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under sections 512(c)(2)(A)(i) and (d)(1)(C), and 571(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(A)(i) and (d)(1)(C), and 360ccc(c)(1)), applicants must submit information on CMC to support the approval of NADAs and ANADAs or the conditional approval of CNADAs. CVM reviews the CMC information for new animal drugs to ensure that applicants have methods and controls in place for manufacturing, processing, and packaging that are adequate for assuring