certain products that contain NAC and are labeled as dietary supplements. The enforcement discretion policy would apply to products that would be lawfully marketed dietary supplements if NAC were not excluded from the definition of ''dietary supplement'' and that are not otherwise in violation of the FD&C Act. Unless we identify safety-related concerns during our ongoing review, FDA would intend to exercise enforcement discretion until either of the following occurs: we complete notice-and-comment rulemaking to allow the use of NAC in or as a dietary supplement (if we move forward with such proceedings), or we deny the citizen petition's request for rulemaking. Should we determine that this enforcement discretion policy is no longer appropriate, we will notify stakeholders by withdrawing or revising this guidance in accordance with 21 CFR 10.115.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/FoodGuidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08560 Filed 4–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1137]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of an FDA guidance document related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidance identified in this notice addresses issues related to the COVID–19 PHE and has been issued in accordance with the process announced in the March 25, 2020, notice. The guidance has been implemented without prior comment, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on April 22, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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 name of the guidance document that the comments address and the docket number for the guidance (see table 1). Received comments will be placed in the docket(s) and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR/2015/09/18/pdf/2015/-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of this guidance to the address noted in table 1. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, as a result of confirmed cases of COVID–19, and after consultation with public health officials as necessary, the Secretary of Health and Human Services (HHS), pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247d), determined that a PHE exists and has existed since January 27, 2020, nationwide.[1] On March 13, 2020, there was a Presidential declaration that the COVID–19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.[2]

In the **Federal Register** of March 25, 2020 (85 FR 16949) (the March 25, 2020, notice) (available at *https://www.govinfo.gov/content/pkg/FR/2020/03/25/pdf/2020/06222.pdf*), FDA announced procedures for making available FDA guidances related to the COVID–19 PHE. These procedures, which operate within FDA's established good guidance practices regulations, are intended to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID–19 to industry, FDA staff, and other stakeholders. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID–19 PHE, FDA believes that prior public participation will not be feasible or appropriate before FDA implements COVID–19-related guidances. Therefore, FDA will issue COVID–19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). The guidances are available on FDA's web pages entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders'' (available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders*) and ''Search for FDA Guidance Documents'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents).*

The March 25, 2020, notice further stated that, in general, rather than publishing a separate NOA for each COVID–19-related guidance, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID–19-related guidances that FDA issued during the relevant period, as included in table 1. This notice announces COVID–19-related guidances that are posted on FDA's website.

II. Availability of COVID–19-Related Guidance Documents

Pursuant to the process described in the March 25, 2020, notice, FDA is announcing the availability of the following COVID–19-related guidance:

TABLE 1—GUIDANCE RELATED TO THE COVID–19 PUBLIC HEALTH EMERGENCY

Docket No.	Center	Title of guidance	Contact information to request single copies
FDA–2020–D–1137	CBER	Emergency Use Authorization for Vaccines to Prevent COVID–19 (Updated March 31, 2022).	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, 1–800–835–4709 or 240–402–8010; email *ocod@fda.hhs.gov*.

Although this guidance has been implemented immediately without prior comment, FDA will consider all comments received and revise the guidance as appropriate (see § 10.115(g)(3)).

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

While this CBER guidance contains no collection of information, it does refer to previously approved FDA collections of information (listed in table 2). Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

TABLE 2—CBER GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
Emergency Use Authorization for Vaccines to Prevent COVID–19 (Updated March 31, 2022).	21 CFR 314.420 ..... 21 CFR part 312 ..... 21 CFR parts 210, 211, and 610	.... 0910–0001. 0910–0014 ..... 0910–0139.	

[1] Secretary of Health and Human Services, ''Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus'' (originally issued on January 31, 2020, and subsequently renewed), available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[2] ''Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak'' (March 13, 2020), available at: *https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.* On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID–19 pandemic beyond March 1, 2021. See ''Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic'' (February 24, 2021), available at *https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic.*

TABLE 2—CBER GUIDANCES AND COLLECTIONS—Continued

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
	21 CFR part 600	.....	0910–0308
	21 CFR part 601	0910–0338.	
		Emergency Use Authorization of Medical Products and Related Authorities.	0910–0595

IV. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at:

- FDA web page entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders;*
- FDA web page entitled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents;* or *https://www.regulations.gov.*

Dated: April 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08564 Filed 4–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0957]

Compliance Policy Guides Sec. 335.500; Sec. 310.200; Sec. 393.100; Sec. 398.425; Sec. 394.500; Sec. 300.750; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of six compliance policy guides (CPG). The Agency is taking this action because the CPGs identified in this notice contain information that is either duplicative of other information the Agency has published or no longer reflects the Agency's current thinking.

DATES: The withdrawal is effective April 22, 2022.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

After careful review of CPGs related to device products, FDA has identified the following six CPGs, that contain information that is either duplicative or no longer reflects the Agency's current thinking.

FDA originally issued CPG Sec. 335.500, ''Razor Blades, Manicuring Instruments—Not Considered Devices Under 201(h)'' (CPG Sec. 335.500) in April 1976. The CPG was revised periodically but has not been revised since March 1995. Given the time that has passed since the last revision of CPG Sec. 335.500, upon further review, FDA has determined that while the CPG still reflects the Agency's current thinking, it is no longer needed because it appears to be seldomly accessed.

CPG Sec. 310.200, ''Sphygmomanometers—Rx Legend'' (CPG Sec. 310.200) was originally issued in January 1973. The CPG was revised periodically but has not been revised since September 1987. Since CPG Sec. 310.200 was last updated, many of these products have been cleared to be sold over the counter and therefore, the policy contained in this CPG is obsolete and no longer needed.

CPG Sec. 393.100, ''Enforcement Policy for Certain Laser Light Shows, Displays, and/or Devices. (21 CFR 1040.10 and 1040.11)'' (CPG Sec 393.100) was originally issued in October 1980. The CPG was revised periodically but has not been revised since March 2005. Since CPG Sec. 393.100 was last revised, the policies regarding these products have been updated and additional resources have been made available to the public regarding these products, including in four laser notice guidance documents.[1] The change in policies and the availability of additional resources has resulted in the information contained within CPG Sec. 393.100 to be duplicative and outdated.

CPG Sec. 398.425, ''Override of Positive Beam Limitation—21 CFR 1020.31(g)(5)'' (CPG Sec. 398.425) was originally issued in October 1980. The CPG was revised periodically but has not been revised since March 2005. Given the time that has passed since the last revision of CPG Sec. 398.425, upon further review, FDA has determined that the CPG provides duplicative information to what is provided in 21 CFR 1020.31(g)(5).

CPG Sec. 394.500, ''Importation of Television Products, Microwave Ovens, and Inherent Class I Laser Products for Investigation and Evaluation during Design Development'' (CPG Sec. 394.500) was originally issued in March 1984. The CPG was revised periodically but has not been revised since July 2004. Given the time that has passed since the last revision of CPG Sec. 394.500, upon further review, FDA has determined that the CPG contains outdated information and references.

Finally, CPG Sec. 300.750, ''Class III Devices Subject to 515(b) Requirements'' (CPG Sec. 300.750) was originally issued in October 1990. The CPG was revised periodically but has not been revised since July 2005. Since CPG Sec. 300.750 was last revised, FDA has completed the actions for the preamendment class III devices discussed in the CPG to either reclassify them into class I, or II, or, if retaining the device in class III, calling for PMAs;[2] as such, the CPG is obsolete.

Therefore, after careful review, FDA is withdrawing CPG Sec. 335.500, CPG Sec. 310.200, 393.100, CPG Sec. 398.425, CPG Sec. 394.500, and CPG Sec. 300.750 in their entirety because the CPGs are either obsolete or contain duplicative information.

Dated: April 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08587 Filed 4–21–22; 8:45 am]

BILLING CODE 4164–01–P

[1] See *https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/laser-light-shows.*

[2] See *https://www.fda.gov/about-fda/cdrh-transparency/515-program-initiative* and *https://www.fda.gov/about-fda/cdrh-transparency/515-project-status.*