

- electroCore, Inc.'s gammaCore Sapphire CV, issued July 10, 2020;<sup>23</sup>
- Michigan State University Animal Care Program's MSU Decontamination System, issued July 24, 2020;<sup>24</sup>
- IkonX, Inc.'s Airway Dome, issued July 24, 2020;<sup>25</sup>
- Abiomed, Inc.'s Impella Left Ventricular (LV) Support Systems, issued August 3, 2020;<sup>26</sup>

(2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CAMIC may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when transporting or performing medical procedures on patients who are known or suspected to have COVID-19, and that the known and potential benefits of the CAMIC for such use outweigh its known and potential risks; and (3) there is no adequate, approved available alternative to the emergency use of the product.

<sup>23</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the gammaCore Sapphire CV may be effective for acute emergency use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their HCP, by using non-invasive Vagus Nerve Stimulation (nVNS) on either side of the patients neck, and that the known and potential benefits of this product for such use outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

<sup>24</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the MSU Decontamination System may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

<sup>25</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Airway Dome may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, at the time of definitive airway management, when performing airway-related medical procedures or during certain transport of patients with suspected or confirmed diagnosis of COVID-19 and that the known and potential benefits of the Airway Dome for such use outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

<sup>26</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes

- Disposable, single-use surgical masks, issued August 5, 2020;<sup>27</sup> A current list of surgical masks authorized by this EUA is available here: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixasurgicalmasks>;
- Baxter Healthcare Corp.'s

Prismaflex HF20 Set, issued August 10, 2020;<sup>28</sup>

- NovaSterilis, Inc.'s Nova2200 using the NovaClean decontamination process for decontaminating compatible N95 respirators, issued August 20, 2020;<sup>29</sup> and

COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Impella LV Support Systems may be effective when used by HCP in the hospital setting for providing temporary LV unloading and support to treat critical care patients with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support, and that the known and potential benefits of the Impella LV Support System, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

<sup>27</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized surgical masks may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of the authorization, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

<sup>28</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness and multiple organ failure, including acute kidney injury, to humans infected by this virus; (2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Prismaflex HF20 Set (cartridge, including hemodialyzer plus tubing set) may be effective at providing continuous renal replacement therapy (CRRT) to treat low weight patients who have low blood volume and who have acute renal failure, fluid overload, or both, and who cannot tolerate a larger extracorporeal circuit volume in an acute care environment during the COVID-19 emergency and that the known and potential benefits of the Prismaflex HF20 Set, when used for such use, outweigh the known and potential risks of the Prismaflex HF20 Set; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

<sup>29</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

- Color Genomics, Inc.'s Color COVID-19 Self-Swab Collection Kit, issued August 31, 2020.<sup>30</sup>

Dated: November 13, 2020.

**Lauren K. Roth,**  
*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-D-2107]

### Cross Labeling Oncology Drugs in Combination Drug Regimens; Draft Guidance for Industry; 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 a draft guidance for industry entitled "Cross Labeling Oncology Drugs in Combination Drug Regimens." This guidance describes FDA's current recommendations on including relevant information in labeling for oncology drugs approved for use in combination drug regimens.

**DATES:** Submit either electronic or written comments on the draft guidance by January 19, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

(2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Nova2200 may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

<sup>30</sup> As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that this product may be effective in diagnosing COVID-19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the self-collected human specimen, and that the known and potential benefits of this product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

### 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 Docket No. FDA-2020-D-2107 for "Cross Labeling Oncology Drugs in Combination Drug Regimens." Received comments will be placed in the docket 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 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. 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:

Marc Theoret, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4099; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

### SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Cross Labeling Oncology Drugs in Combination Drug Regimens." This guidance describes FDA's current recommendations on including relevant information in labeling for oncology drugs approved for use in combination drug regimens.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Cross Labeling Oncology Drugs in Combination Drug Regimens." 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.

#### II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. 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 collection of information in 21 CFR part 314, including the submission of labeling under 21 CFR 314.50(e)(2)(ii) and (l)(1)(i), and the submission of new drug applications (NDAs) and supplemental NDAs, has been approved under OMB control number 0910-0001. The content and format of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910-0572. The collection of information in the Guidance for Industry on Formal Meetings between FDA and Sponsors and Applicants for PDUFA Products has been approved under OMB control number 0910-0429.

#### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>, or <https://www.regulations.gov>.

Dated: November 9, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Indian Health Service**

#### **National Urban Indian Behavioral Health Awareness**

*Announcement Type:* New/Competing Continuation.

*Funding Announcement Number:* HHS-2020-IHS-UIHP3-0001.

*Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number:* 93.193.

#### **Key Dates**

*Application Deadline Date:* December 21, 2020.

*Earliest Anticipated Start Date:* January 4, 2021.

#### **I. Funding Opportunity Description**

##### *Statutory Authority*

The Indian Health Service (IHS) is accepting applications for a cooperative agreement for Urban Indian Behavioral Health. This program is authorized under: Snyder Act, codified at 25 U.S.C. 13; the Transfer Act, codified at 42 U.S.C. 2001; the Consolidated Appropriations Act, 2020, Public Law 116-94, 133 Stat. 2534 (2020). This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.193.

##### *Background*

The Office of Clinical and Preventive Services, Division of Behavioral Health (DBH) serves as the primary source of national advocacy, policy development, management and administration of behavioral health, alcohol and substance abuse, and family violence prevention programs. Working in partnership with Tribes, Tribal organizations, and Urban Indian Organizations (UIO), DBH coordinates national efforts to share knowledge and build capacity through the development and implementation of evidence/practice based and cultural-based practices in Indian Country.

##### *Purpose*

The purpose of this IHS program is to increase the awareness, visibility, advocacy, and education for behavioral health issues on a national scale and in the interest of improving urban Indian

health care. This program is in alignment with the 2019-2023 IHS Strategic Plan Goal 1: To ensure that comprehensive, culturally appropriate personal and public health services are available and accessible to American Indian and Alaska Native (AI/AN) people, Objective 1.2: Build, strengthen, and sustain collaborative relationships; and Goal 2: To promote excellence and quality through innovation of the Indian health system into an optimally performing organization, Objective 2.2: Provide care to better meet the health care needs of American Indian and Alaska Native communities. Urban Indian Organizations are defined by 25 U.S.C. 1603(29) as a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities describes in 25 U.S.C. 1653(a). The awardee's activities funded under this cooperative agreement must be intended to support all organizations that meet the statutory definition of UIO.

##### *Pre-Conference Grant Requirements*

The awardee is required to comply with the "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications," dated January 23, 2015 (Policy), as applicable to conferences funded by grants and cooperative agreements. The Policy is available at <https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html?language=es>.

The awardee is required to: Provide a separate detailed budget justification and narrative for each conference anticipated. The cost categories to be addressed are as follows: (1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration website, (4) Audio Visual, (5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, (8) Other (explain in detail and cost breakdown). For additional questions please contact Sarah Tillman at (301) 605-3504 or email her at [sarah.tillman@ihs.gov](mailto:sarah.tillman@ihs.gov).

#### **II. Award Information**

##### *Funding Instrument*

Cooperative Agreement.

##### *Estimated Funds Available*

The total funding identified for fiscal year (FY) 2020 is approximately

\$75,000. The funding available for competing and subsequent continuation award issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

##### *Anticipated Number of Awards*

One award will be issued under this program announcement.

##### *Project Period*

The project period is for three years.

##### *Cooperative Agreement*

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. However, the funding agency, IHS, is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement from IHS.

##### *Substantial Involvement Description for Cooperative Agreement*

##### *IHS Programmatic Involvement*

The IHS assigned program official will monitor the overall progress of the awardee's execution of the requirements of the award noted below as well as their adherence to the terms and conditions of the cooperative agreements. This includes providing guidance for required reports, developing tools and other products, interpreting program findings, assisting with evaluations, and overcoming any difficulties or performance issues encountered. The IHS assigned program official must approve all presentations, electronic content, mass emails, and other materials developed by awardee pursuant to this award and any supplemental award prior to the presentation or dissemination of such materials to any party.

#### **III. Eligibility Information**

##### *1. Eligibility*

To be eligible for this "New/Competing Continuation Announcement" an eligible applicant must be a 501(c)(3) organization that has demonstrated expertise as follows:

- Representing urban Indians and providing a variety of services to urban Indians and Federal agencies with an established major role in focusing attention on urban Indian health care needs.
- Promoting and supporting health education for urban Indians and