

- Certain Protective Barrier Enclosures, issued May 1, 2020;<sup>19</sup>
- PhsiolGuard Corp. Ltd.'s Physiologuard ECG–QT Analysis System, issued May 5, 2020 (refer to footnote 15);
- Duke University Health System's Duke Decontamination System, issued May 7, 2020;<sup>20</sup>
- Comunale's Patient Isolation Transport Unit, issued May 8, 2020;<sup>21</sup>

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 VentFree may be effective for emergency use by HCP in healthcare settings to treat adult patients by reducing disease atrophy of the abdominal wall muscles, which may reduce the number of days of ventilator support in patients who require mechanical ventilation during the COVID–19 pandemic, and that the known and potential benefits of the such products, 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 this product.

<sup>19</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 protective barrier enclosures may be effective at preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when caring for or performing medical procedures on patients who are known or suspected to have COVID–19 in healthcare settings and that the known and potential benefits of protective barrier enclosures, 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 this product.

<sup>20</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 Duke Decontamination System may be effective at decontaminating compatible N95 respirators for reuse by HCPs 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 as described, 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 this product.

<sup>21</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 PITU may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in

- Ascom (US) Inc.'s teleCARE IP Nurse Call System, issued May 11, 2020;<sup>22</sup>
- Eko Devices, Inc.'s Eko ELEFT, issued May 11, 2020;<sup>23</sup>
- Certain Infusion Pumps and Infusion Pump Accessories, issued May 13, 2020;<sup>24</sup>
- G Medical Innovations Ltd.'s VSMS Patch, issued May 14, 2020;<sup>25</sup> and

addition to PPE, outweigh the known and potential risks of the PITU; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

<sup>22</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 use of the teleCARE IP Nurse Call System in healthcare environments may be effective for preventing COVID–19 exposure in healthcare providers by enabling remote communication between patients and healthcare providers, and, for those patients utilizing a ventilator, remote monitoring of ventilator status updates to alert the healthcare provider. FDA concluded that the known and potential benefits of the teleCARE IP Nurse Call System, for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of this 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 ELEFT may be effective for use by HCP to provide an assessment of LVEF for use as a diagnostic aid to screen for potential cardiac complications associated with COVID–19 or underlying cardiac conditions that may affect clinical management of COVID–19, in adult patients having or suspected of having COVID–19 and that the known and potential benefits of ELEFT, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this 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 authorized infusion pumps and infusion pump accessories may be effective for use by HCPs to treat conditions caused by COVID–19 with the controlled infusion of medications, TPN, and/or other fluids, and that the known and potential benefits of such products, for such use outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

<sup>25</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 the VSMS Patch may be effective in remotely monitoring QT interval prolongation on an ECG in patients who are undergoing treatment in a hospital setting for COVID–19 with drugs that can prolong QT intervals and may cause life-threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination

- Everlywell Inc.'s Everlywell COVID–19 Test Home Collection Kit, issued May 15, 2020.<sup>26</sup>

Dated: July 8, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2020–N–1313]

#### Electronic Submissions; Data Standards; Support for Standard for the Exchange of Nonclinical Data

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) Center for Biologics Evaluation and Research (CBER) is announcing support for the current version of Clinical Data Interchange Standards Consortium (CDISC) Standard for the Exchange of Nonclinical Data (SEND) and an update to the FDA Data Standards Catalog for the submission of nonclinical data in new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs). This update does not apply to noncommercial INDs for a product that is not intended for commercial distribution (research and investigator-sponsored INDs); INDs and BLAs for devices that are regulated by CBER as biological products under the Public Health Services (PHS) Act; and submissions for blood and blood components, including Source Plasma.

with azithromycin), the known and potential benefits of the VSMS Patch, for such use, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of this product.

<sup>26</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 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 home-collected human specimen, and that the known and potential benefits of the product when used for such use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

**ADDRESSES:** You may submit either electronic or written comments 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 Docket No. FDA-2020-N-1313 for "Electronic Submissions; Data Standards; Support for Standard for the Exchange of Nonclinical Data." 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.

- **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 laws. 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.

**FOR FURTHER INFORMATION CONTACT:** Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:** CBER is announcing support for the current version of CDISC SEND and an update to the FDA Data Standards Catalog for the submission of nonclinical data in NDAs, ANDAs, BLAs, and certain INDs. This update does not apply to: (1) Noncommercial INDs for a product that is not intended for commercial distribution (research and investigator-sponsored INDs); (2) INDs and BLAs for devices that are regulated by CBER as biological products under section 351 of the PHS Act (42 U.S.C. 262); and (3) submissions for blood and blood components, including Source Plasma. In section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1(a)), Congress granted explicit statutory authorization to FDA

to specify in guidance the format for the electronic submissions required under that section.

In the **Federal Register** of December 18, 2014 (79 FR 75568), FDA announced a final guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Standardized Study Data." The guidance is available on FDA's Study Data Standards Resources web page at <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>. The guidance implemented the electronic submission requirements of section 745A(a) of the FD&C Act for study data contained in NDAs, ANDAs, BLAs, applications under subsection (a) or (k) of section 351 of the PHS Act, and certain INDs. The initial timetable for the implementation of electronic submission requirements for study data was December 17, 2016. The guidance states that a **Federal Register** notice will specify the transition date for all new standards (with the month and day for the transition date corresponding to March 15).

The transition date for support of CDISC SEND is March 15, 2021, for CBER. Although SEND is now supported by CBER and sponsors or applicants are encouraged to begin using it, the SEND standard will only be required in studies that start 24 months after the transition date of March 15, 2021. The Catalog will list March 15, 2023, as the "date requirement begins" for CBER. When multiple versions of an FDA-supported standard are listed in the Catalog, sponsors or applicants can select a version to use.

Dated: July 8, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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

### **Food and Drug Administration**

[Docket No. FDA-2016-D-3004]

#### **Use of The Seafood List To Determine Acceptable Seafood Names; Compliance Policy Guide; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for FDA staff entitled "Compliance Policy Guide Sec. 540.750