4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0577]

Authorization of Emergency Use of a Drug Product During the COVID-19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for use during the COVID-19 pandemic. FDA has issued an Authorization for the drug product GOHIBIC (vilobelimab) as requested by InflaRx GmbH's (InflaRx). The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS), as amended on March 15, 2023, that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS-CoV-2, causes the illness COVID-19. On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of April 4, 2023.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Johanna McLatchy, Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993-0002, 301-796-3200 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including

personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces;[1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the *Federal Register* a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on FDA's website. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355,

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA[2] concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorization

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

The Authorization follows the February 4, 2020, determination by the Secretary of HHS, as amended on March 15, 2023, that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS-CoV-2, causes the illness COVID-19. Notice of the Secretary's determination was provided in the *Federal Register* on February 7, 2020 (85 FR 7316) and notice of the Secretary's amended determination was provided in the *Federal Register* on March 20, 2023 (88 FR 16644). On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the *Federal Register* on April 1, 2020 (85 FR 18250). Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, on April 4, 2023, FDA issued an EUA to InflaRx for the drug product GOHIBIC (vilobelimab), subject to the terms of the Authorization. The initial Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuance of the Authorization can be found on FDA's web page at: https://www.fda.gov/drugs/emergency-preparedness-drugs/emergency-use-authorizations-drugs-and-non-vaccine-biological-products.

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

April 12, 2023

InflaRx GmbH
c/o Dunn Regulatory Associates, LLC
Dana Dunn, MS
President, Dunn Regulatory Associates, LLC
2709 Silkwood Court
Oakton, VA 22124

RE: Emergency Use Authorization 118

Dear Ms. Dunn:

This letter is in response to InflaRx GmbH's (InflaRx) request that the Food and Drug Administration (FDA or Agency) issue an Emergency Use Authorization (EUA) for the emergency use of GOHIBIC (vilobelimab) for the treatment of coronavirus disease 2019 (COVID-19) in certain hospitalized adult patients, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, as amended on March 15, 2023, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. February 4, 2020; U.S. Department of Health and Human Services, *Amended Determination of a Public Health Emergency or Significant Potential for a Public Health Emergency Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)*. March 15, 2023. 88 FR 16644 (March 20, 2023) ("Amended Determination").

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020). *See* Amended Determination ("The declarations issued pursuant to section 564(b)(1) of the FD&C Act that circumstances exist justifying the authorization of emergency use of certain in vitro diagnostics, personal respiratory protective devices, other medical devices and drugs and biological products, as set forth in those declarations, and that are based on the February 4, 2020 determination, remain in effect until those declarations are terminated in accordance with section 564 of the FD&C Act.").

On April 4, 2023, FDA issued an EUA for emergency use of GOHIBIC for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO).

GOHIBIC is a recombinant chimeric monoclonal IgG4 antibody that specifically binds to the soluble human complement split product C5a after cleavage from C5 to block its interaction with the C5a receptor, both of which are components of the complement system thought to contribute to inflammation and worsening of COVID-19. GOHIBIC is not FDA-approved for any indication, including for the treatment of COVID-19.

On April 12, 2023, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA is reissuing the April 4, 2023 letter in its entirety, to revise condition H to include additional language on product recall and to incorporate condition J detailing requirements on registration and listing.

Based on the totality of scientific evidence available to FDA, including data from the Phase 3 portion of the clinical trial, PANAMO (NCT04333420): a randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of GOHIBIC in adult (≥18 years) patients with COVID-19 pneumonia who required IMV or ECMO, it is reasonable to believe that GOHIBIC may be effective for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO, as described in the Scope of Authorization (Section II), and when used under the conditions described in this authorization, the known and potential benefits of GOHIBIC outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of GOHIBIC for the treatment COVID-19 in certain hospitalized adults, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of GOHIBIC for the treatment of COVID-19, when administered as described in the Scope of Authorization (Section II), meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

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 GOHIBIC may be effective for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO, as described in the Scope of Authorization (Section II), and that, when used under the conditions described in this authorization, the known and potential benefits of GOHIBIC outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of GOHIBIC for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO.[3,4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- GOHIBIC may only be used by healthcare providers for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO.

- The use of GOHIBIC covered by this authorization must be in accordance with the authorized Fact Sheets.

Product Description

GOHIBIC 200 mg/20 mL (10 mg/mL) is a clear to slightly opalescent, colorless solution that is supplied in a single-dose vial (NDC 83000-110-04) for intravenous administration after dilution.

The authorized storage and handling information for GOHIBIC is included in the authorized Fact Sheet for Healthcare Providers.

GOHIBIC is authorized for emergency use with the following product-specific information required to be made available to healthcare providers and to patients and caregivers, respectively, through InflaRx's website at www.gohibic.com (referred to as the "authorized labeling"):

- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) for GOHIBIC
- Fact Sheet for Patients and Caregivers: Emergency Use Authorization (EUA) of GOHIBIC for Coronavirus Disease 2019 (COVID-19)

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[4] Veklury (remdesivir), a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor, is an FDA-approved alternative for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO. Veklury has demonstrated antiviral activity against SARS-CoV-2; whereas GOHIBIC acts by binding to C5a to block its interaction with the C5a receptor, both of which are components of the complement system thought to contribute to inflammation and worsening of COVID-19, offering a different mechanism of action. Olumiant (baricitinib), a Janus kinase (JAK) inhibitor, is an FDA-approved alternative for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of requiring IMV, or ECMO. As noted, GOHIBIC offers a different mechanism of action. In addition, GOHIBIC has an intravenous route of administration; whereas, Olumiant is available as tablets, offering an alternative route of administration to adult patients who are mechanically ventilated or on ECMO. Actemra, an interleukin-6 (IL-6) receptor antagonist, is also an FDA-approved alternative for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO. As noted, GOHIBIC offers a different mechanism of action.

I have concluded, pursuant to Section 564(d)(2) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the known and potential benefits of GOHIBIC, when used for the treatment of COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh the known and potential risks, pursuant to Section 564(c)(2)(B) of the Act.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that GOHIBIC may be effective for the treatment of COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that GOHIBIC (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of GOHIBIC under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), GOHIBIC is authorized for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO, as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

InflaRx and Authorized Distributors[5]

A. InflaRx and authorized distributor(s) will ensure that GOHIBIC is distributed and the authorized labeling (i.e., Fact Sheets) will be made available to healthcare facilities and/or healthcare providers as described in Section II of this Letter of Authorization.

B. InflaRx and authorized distributor(s) will ensure that appropriate storage is maintained until the product is delivered to healthcare facilities and/or healthcare providers.

C. InflaRx and authorized distributor(s) will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving GOHIBIC. InflaRx will provide to all relevant stakeholders a copy of this Letter of Authorization and communicate any subsequent

[5] "Authorized Distributor(s)" are identified by InflaRx as an entity or entities allowed to distribute the authorized GOHIBIC.

amendments that might be made to this Letter of Authorization and its authorized accompanying materials (i.e., Fact Sheets).

D. InflaRx may request changes to this authorization, including to the authorized Fact Sheets for GOHIBIC. Any request for changes to this EUA must be submitted to the Office of Immunology and Inflammation/Office of New Drugs/Center for Drug Evaluation and Research. Such changes require appropriate authorization prior to implementation.[6]

E. InflaRx may develop and disseminate instructional and educational materials (e.g., materials providing information on product administration and/or patient monitoring) that are consistent with the authorized emergency use of GOHIBIC as described in this Letter of Authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs. Any instructional and educational materials that are inconsistent with the authorized labeling for GOHIBIC are prohibited. If the Agency notifies InflaRx that any instructional and educational materials are inconsistent with the authorized labeling, InflaRx must cease distribution of such instructional and educational materials. Furthermore, as part of its notification, the Agency may also require InflaRx to issue corrective communication(s).

F. InflaRx will report to FDA all serious adverse events and medication errors potentially related to GOHIBIC use that are reported to InflaRx using either of the following options.

Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

Submitted reports under both options must state: "GOHIBIC use for COVID-19 under Emergency Use Authorization (EUA)." For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

G. All manufacturing, packaging, and testing sites for both drug substance and drug product used for EUA supply will comply with current good manufacturing practice requirements of Section 501(a)(2)(B) of the Act.

[6] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study; (8) new strengths of the authorized product, new product sources (e.g., of active pharmaceutical ingredient) or of product components. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), (7), or (8), review and concurrence is required from the Counter-Terrorism and Emergency Coordination Staff/Office of the Center Director/CDER and the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

H. InflaRx will submit information to the Agency within three working days of receipt of any information concerning significant quality problems with drug product distributed under this EUA for GOHIBIC that includes the following:

- Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or
- Information concerning any microbiological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the product to meet the established specifications.

If a significant quality problem affects unreleased product and may also impact product(s) previously released and distributed, then information must be submitted for all potentially impacted lots.

InflaRx will include in its notification to the Agency whether the batch, or batches, in question will be recalled. If FDA requests that these, or any other batches, at any time, be recalled, InflaRx must recall them.

If not included in its initial notification, InflaRx must submit information confirming that InflaRx has identified the root cause of the significant quality problems, taken corrective action, and provide a justification confirming that the corrective action is appropriate and effective. InflaRx must submit this information as soon as possible but no later than 45 calendar days from the initial notification.

I. InflaRx will manufacture GOHIBIC to meet all quality standards and per the manufacturing process and control strategy as detailed in InflaRx's EUA request. InflaRx will not implement any changes to the description of the product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product, without notification to and concurrence by the Agency as described under Condition D.

J. InflaRx will list each presentation of GOHIBIC with a unique product NDC under the marketing category of Emergency Use Authorization. Further, the listing will include each establishment where manufacturing is performed for the drug and the type of operation performed at each such establishment.

K. Through a process of inventory control, InflaRx and authorized distributor(s) will maintain records regarding distribution of GOHIBIC (i.e., lot numbers, quantity, receiving site, receipt date).

L. InflaRx and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Facilities to Whom GOHIBIC Is Distributed and Healthcare Providers Administering GOHIBIC

M. Healthcare facilities and healthcare providers will ensure that they are aware of the Letter of Authorization, and the terms herein, and that the authorized Fact Sheets are made available to healthcare providers and to patients and caregivers, respectively, through appropriate means, prior to administration of GOHIBIC as described in the Scope of Authorization (Section II) under this EUA.

N. Healthcare facilities and healthcare providers receiving GOHIBIC will track all serious adverse events and medication errors that are considered to be potentially related to GOHIBIC use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports must state, "GOHIBIC use for COVID-19 under Emergency Use Authorization" at the beginning of the question "Describe Event" for further analysis. A copy of the completed FDA Form 3500 must also be provided to InflaRx per the instructions in the authorized labeling.

O. Healthcare facilities and healthcare providers will ensure that appropriate storage is maintained until the product is administered consistent with the terms of this letter and the authorized labeling.

P. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensing and administration of GOHIBIC for the use authorized in this letter (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

Q. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by InflaRx and/or FDA. Such records will be made available to InflaRx, HHS, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

R. All descriptive printed matter, advertising, and promotional materials relating to the use of GOHIBIC under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the Act, as applicable, and FDA implementing regulations. References to "approved labeling", "permitted labeling", or similar terms in these requirements shall be understood to refer to the authorized labeling for the use of GOHIBIC under this authorization. In addition, such materials shall:

- Be tailored to the intended audience.

- Not take the form of reminder advertisements, as that term is described in 21 CFR 202.1(e)(2)(i), 21 CFR 200.200 and 21 CFR 201.100(f).
- Present the same risk information relating to the major side effects and contraindications concurrently in the audio and visual parts of the presentation for advertising and promotional materials in audio-visual format.
- Be accompanied by the authorized labeling, if the promotional materials are not subject to Section 502(n) of the Act.
- Be submitted to FDA accompanied by Form FDA-2253 for consideration at least 14 calendar days prior to initial dissemination or first use.

S. InflaRx may disseminate descriptive printed matter, advertising, and promotional materials relating to the emergency use of GOHIBIC that provide accurate descriptions of safety results and efficacy results on a clinical endpoint(s) from the clinical trial(s) summarized in the authorized labeling. Such materials must include any limitations of the clinical trial data as described in the authorized labeling. InflaRx may not imply that GOHIBIC is FDA-approved for its authorized use by making statements such as "GOHIBIC is safe and effective for the treatment of COVID-19."

T. All descriptive printed matter, advertising, and promotional material, relating to the use of GOHIBIC under this authorization clearly and conspicuously shall state that:

- GOHIBIC has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving IMV, or ECMO; and
- The emergency use of GOHIBIC is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

If the Agency notifies InflaRx that any descriptive printed matter, advertising, or promotional materials do not meet the terms set forth in Conditions R through T of this EUA, InflaRx must cease distribution of such descriptive printed matter, advertising, or promotional materials in accordance with the Agency's notification. Furthermore, as part of its notification, the Agency may also require InflaRx to issue corrective communication(s).

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Patrizia A. Cavazzoni -S

Digitally signed by Patrizia A. Cavazzoni -S
Date: 2023.04.12 09:27:59 -04'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dated: May 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-11852 Filed: 6/2/2023 8:45 am; Publication Date: 6/5/2023]