Pre-Emergency Use Authorization (EUA)/EUA Interactive Review Template For Non-IVD Products

This interactive review template (the "template") was designed to capture the data/information needed by the Food and Drug Administration (FDA) to support authorization of a product for emergency use during the COVID-19 pandemic. This template is intended to help companies provide the information to FDA, but alternative approaches can be used. For more information about EUAs in general, refer to the FDA Guidance document: *Emergency Use Authorization of Medical Products and Related Authorities*. ***Once completed, please send this interactive review template to*** **CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov.**

GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow [text] should be completed by the medical device product developer ("sponsor") as applicable to its specific product. Text in **bold** outlines the FDA's suggestions and clarifications for the sponsor to consider when completing the information in each section.

- This is a template for Pre-EUA/EUA submissions and not a guidance document. It includes the information that FDA recommends be included in such submissions, as outlined in the *Emergency Use Authorization of Medical Products and Related Authorities* Guidance document. This template is subject to change as we learn more about COVID-19 generally or improve the EUA review process.

- Any trade secret or confidential commercial information provided within the template and during the interactive review process will remain confidential.

- Feedback provided by FDA during the interactive review of a pre-EUA/EUA submission is subject to change as FDA gains experience during an emergency, and as FDA learns more about the disease/condition this device addresses.

- Please remember that if an EUA is issued for your product, the authorization would only be for the use specified in the EUA and subject to the conditions in the EUA. This device must not be introduced into interstate commerce for uses outside the authorized use without obtaining marketing clearance, approval, IDE, or another EUA by the FDA.

- Clinical data may be required to support an EUA request. Please note that human subject protection requirements (21 CFR Part 50) apply to clinical trials conducted to support an EUA.

- If authorized, the EUA means that the product would be authorized for use until the declaration of public health emergency is terminated, or the EUA is revoked by the FDA.

- ***The EUA is not a pathway to permanent marketing of your product.*** For information on premarket submissions, refer to FDA's website on "How to Study and Market Your Device" at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device. For guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to FDA guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device*.

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A. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the [***Name of Medical Device Product ("product")***] to ***indicate end user(s) (e.g., patients, hospitals); brief summary of intended use for product (e.g., prevention/diagnosis /treatment);*** *and* ***description of the intended patient population***]

B. APPLICANT

Applicant information:

- Applicant Company Name:
- Applicant Address:
- Applicant Contact Person:
- Applicant Contact Phone#:
- Applicant Contact Email:

Correspondent information (if different from the Applicant):

- Correspondent Company Name:
- Correspondent Address:
- Correspondent Contact Person:
- Correspondent Contact Phone#:
- Correspondent Contact Email:

C. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - ***[product trade name]***
Established Name - ***[generic name]***

D. INTENDED USE

1) Proposed Intended Use of the Product

[Include the proposed intended use for the product that is subject of this request.] The intended use will be finalized based on the data and recommendations at the time of authorization.

2) Special Conditions of Use Statements:

[Include any special conditions of use statements to be included in the product labeling, e.g., "For prescription use only" and other specific conditions]

E. REGULATORY INFORMATION

1) Marketing authorization in the U.S.

Previous regulatory submissions (including application number) [510(k), De Novo, PMA, HDE, IDE]:

[Include any prior regulatory history for this product. Indicate whether the product is legally marketed in the US. If so, include the premarket submission number(s). If applicable, include a description of any modifications made to the legally marketed product.]

[If no prior clearances or approvals, including under an investigational product exemption (IDE) application, include the following statement:

The [***Name of Product***] is not cleared or approved for introduction into interstate commerce nor subject to an approved IDE application.]

Pending application(s) currently under review:

[Indicate whether the product has any pending regulatory submission with FDA.]

2) Marketing authorizations in any other country:

Indicate whether the product currently has marketing authorization in another regulatory jurisdiction, such as the European CE Mark, Australian Register of Therapeutic Goods (ARTG) Certificate of Inclusion, Health Canada License, or Shonin approval from the Ministry of Health, Labour, and Welfare in Japan, and attach any relevant documentation, such as the marketing authorization letter or certificate, or corresponding information such as the certificate of conformity.

F. PRODUCT DESCRIPTION AND PRINCIPLE

[Include a detailed description of the product.] Please note that for new technologies FDA may request additional detailed information so we can adequately assess the known and potential risks and benefits associated with the product.

1) Product Overview/Product Principle:

[Describe the technology of the **[Type of Product]** and how this technology works to **[include intended use]** the **[pathogen/disease/condition].**]

2) Detailed Description of Product Use:

[List and describe in detail all the steps involved in using the product. Include a detailed description of how the end user uses the product; capture the key product description information related to the product function.]

3) Applicable Standards

[Indicate whether the product has been designed, evaluated, and validated in accordance with the applicable FDA-recognized standards.]

4) [Include Any Other Important Topics Necessary to Describe the Product]:

[If applicable, include additional sections concerning other topics about the product design and use that are important to capture, for example if calibration of the product is required, or special features of the product. This section may also include literature provided to support the intended use. Otherwise, indicate this section is N/A.]

G. PRODUCT MANUFACTURING AND PLANNED DISTRIBUTION

[Include a detailed description of the product manufacturing and distribution.]

1) Overview of Manufacturing and Distribution:

[Include an overview of the manufacturing and planned distribution of the product. Include where the product will be manufactured, including whether it will be manufactured inside the United States or manufactured outside the United States and then imported.]

2) Quality System

[Indicate whether the product is manufactured in compliance with 21 CFR Part 820 or ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes,* or an equivalent quality system, and the manufacturer or importer has documentation of such.]

3) Components Included with the Product

[List all components provided with/for your product].

4) Other Components Not Included with the Product

[List all components not included with the product that should be supplied by the user to use the product, with specific supplier names and catalog numbers, product characteristics, or other identifiers for obtaining these components.

5) [Other Important Topics to Describe]:

[If applicable, include additional sections concerning other topics about the product manufacturing that are important to capture. Otherwise, indicate this section is N/A.]

6) **Product Stability/Shelf Life:**
Briefly describe the stability/shelf-life test plan for the product and include any accelerated stability/shelf life information (if available). Briefly describe any standards used to evaluate product stability/shelf-life (e.g., ASTM F1980).

H. EVIDENCE OF POTENTIAL EFFECTIVENESS

[During Interactive Review, you may be requested to provide line item data, protocols and reports to support that the product may be effective.]

[Include data (including bench, animal and/or clinical) you have collected to support the emergency use of your product.]

I. APPROVED/CLEARED ALTERNATIVE PRODUCTS

[FDA and/or the Sponsor can provide a summary of the currently approved/cleared alternative products. If appropriate, sponsors can use the following statement:]

Currently no methods for the [prevention/diagnosis/treatment] of the **[*pathogen/disease/condition*]** have been approved/ cleared by FDA.

J. UNMET NEED ADDRESSED BY THE PRODUCT

[This section will be finalized by FDA based on the state of the emergency at the time of authorization and based on recommendations from public health authorities at that time. Include an explanation of the unmet need of the product.]

A public health emergency has been declared by the Secretary of Health and Human Services (HHS) on [Month Day, YEAR] justifying the authorization of emergency use of [Type of Product] for [state the intended use of the product].

The ***[product name]*** can [outline how product can aid in the public health response].

Under emergency use authorization (EUA), ***[applicant name]*** plans to distribute the ***[product name]*** for the [prevention/diagnosis/treatment] of [pathogen/disease/condition] in individuals meeting CDC's [pathogen/disease/condition] clinical and/or epidemiological criteria. This EUA request for the ***[product name]*** is intended to expand domestic readiness within the United States and its territories by expanding [prevention/diagnosis/treatment] capabilities for [pathogen/disease/condition] during public health emergency.

FDA consulted with subject matter experts within HHS on the public health needs for [Type of Product] to [prevent/diagnose/treat] the [pathogen/disease/condition]. It is FDA's conclusion that there currently exists a public health need for such products, i.e., that there is no adequate, approved (cleared), and available alternative to the ***[product***

name] for [pathogen/disease/condition] [prevention/diagnosis/treatment] during the public health emergency.

K. RISKS AND BENEFITS:

Update this section according to your specific product, some example language is given below but should be tailored to the product and the disease.

[This is a key section of the EUA Interactive Review Template that outlines the risk-benefit analysis. Fill out this section based on your risk-benefit analysis, however, there may be other key elements that FDA may request based on its review of the information provided.

Risks
The known and potential risks of the ***[product name]*** are:

- [X]
  - [X]

Benefits
The known and potential benefit of the ***[product name]*** for clinical use [X] are:

- [X]
  - [X]

[Include a discussion on the criterion related to known and potential benefits outweighing known and potential risks, taking into consideration the material threat posed by COVID-19.]

L. FACT SHEET FOR HEALTHCARE PROVIDERS AND PATIENTS

[Include proposed Fact Sheets for Patients and Healthcare Providers. Sponsors are encouraged to review other Fact Sheets on the CDRH EUA Website as examples.]

M. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT

[Include Instructions for Use, Box Labels, Product Labels and any other proposed labeling.]

N. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

[Include a description of the record keeping and reporting for the product. Example language is provided below.]

[***Manufacturer name***] will track adverse events and report to FDA. A website is available to report on adverse events, and this website is referenced in the Fact Sheet for Health Care providers as well as through the [***Manufacturer name***] Product Support website: [***Include link to Website***]. Each report of an adverse event will be processed

according to [***Manufacturer name]***'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, [***Manufacturer name]*** will also maintain records of product usage/purchase. [***Manufacturer name]*** will collect information on the performance of the [product], and report to FDA any suspected occurrence of product malfunctions of which [***Manufacturer name]*** becomes aware. [***Manufacturer name]*** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

O. FDA SUMMARY OF DOCUMENTATION AND REVIEW [for FDA Internal Use Only]

[FDA reviewers will include a brief summary of the documentation provided and their conclusion of whether the product meets the EUA criteria outlined in section 564 of the Food, Drug, and Cosmetic Act. The FDA reviewer should include a statement regarding the known and potential benefits from the use of the ***[product name]*** for ***[intended use of the product under this EUA]*** are expected to outweigh the known and potential risks.

FDA reviewers should clearly distinguish their comments and edits in the document from the information provided by the sponsor.]

P. INTERACTIVE REVIEW LOG:

Use the table below to document interactive review, include interactions initiated by either FDA or the sponsor.

Date	**Type of Interaction** (phone/ email/ formal submission-DCC)	**Brief Description** (e.g., questions asked/ feedback from FDA received / any word documents included)
[X]	[X]	[X]

Q. NEXT STEPS:

Once FDA review is completed, FDA will notify the sponsor regarding the status of the pre-EUA/EUA. Please note that, as set forth in FDA's guidance Emergency Use Authorization of Medical Products and Related Authorities, FDA intends to prioritize its review of EUA requests during a declared emergency based on various factors, including the extent to which the product would serve a significant unmet medical need.

R. FINALIZING REVIEW

Once FDA review is completed, FDA reviewers should finalize the documentation, sign and date the Interactive Review Template (which will serve as the FDA review memo for the pre-EUA/EUA), and document concurrence from the OHT management.