Subject: 2020-3157
Date: Tuesday, August 22, 2023 at 3:03:14 PM Eastern Daylight Time
From: Kotler, Sarah
To: FOIA
Attachments: RELEASE 2020-3157 Boxed Combined Records_Redacted.pdf

EXTERNAL SENDER

Dear Requester,

The records you are seeking are attached.

Certain information has been redacted from the records under Exemption 5 of the FOIA (deliberative process information) and Exemption 6 of the FOIA (personal privacy information). In determining to withhold such information, FDA considered 5 USC 552(a)(8)(i), when applicable, and whether FDA reasonably foresees that disclosure of such information would harm an interest protected by the relevant exemption(s) and whether disclosure is prohibited by law.

You have the right to appeal this determination. Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency's adverse determination should be reconsidered. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, U.S. Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, or emailed within 90 days from the date of this response to FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Meredith Schlaifer at 301-796-0583. You may also contact the FDA FOIA Public Liaison for assistance at: Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

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Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

Sincerely,

Sarah Kotler

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From: Ziegler, Garrett M. EOP/WHO (b) (6)
Sent: 4/16/2020 12:18:11 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Request for FDA Hydroxi Notice

Thank you very much, Colin. Will make sure Dr. Navarro reads these. Appreciate you all working so quickly to put this out.

Kind regards,

Garrett

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 5:50 PM
To: Ziegler, Garrett M. EOP/WHO (b) (6)
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: Request for FDA Hydroxi Notice

Hey Garrett—

Below are some fact sheets that have been posted on FDA's website. Let me know if this is helpful for what Peter had requested below.

Allows hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible. These drugs will be distributed from the SNS to states for doctors to prescribe to these patients.
>https://www.fda.gov/media/136536/download<

>https://www.fda.gov/media/136538/download<

Thanks!

From: Navarro, Peter K. EOP/WHO (b) (6) >
Date: April 9, 2020 at 1:05:52 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Request for FDA Hydroxi Notice

Steven, good to see you yesterday. As we discussed, maybe refresh 28 March EUA for Chloroquine phosphate / Hydroxychloroquine sulfate (HCQ) issued by the FDA for the management of COVID-19 infections. Based on the gathered intelligence that we make as we distribute HCQ for COVID-19 use, we note that the drug is being used across the patient spectrum, from early and moderate cases, to very severe cases. The only end-point we have at this time is the % of patient survival for all HCQ-treated cases. We believe it would be useful for a FDA and CDC to (b) (5)

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Peter Navarro, Assistant to the President for Trade & Manufacturing Policy (b) (6)

The President's two simple rules: "Buy American, Hire American."

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From: Williams, James H. EOP/WHO (b) (6)
Sent: 6/11/2020 10:46:11 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
CC: Merkel, Theo W. EOP/WHO (b) (6)]; D'Angelo, Gregory B. EOP/OMB (b) (6)]; Overton, Heidi N. EOP/WHO (b) (6); Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: Follow up

Thank you, all. This is very helpful.

On Jun 11, 2020, at 6:35 PM, Abram, Anna <Anna.Abram@fda.hhs.gov> wrote:

Thanks, Theo. Let me check with the team to see what we have. Will loop back.

From: Merkel, Theo W. EOP/WHO (b) (6)>
Date: June 11, 2020 at 6:17:15 PM EDT
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, D'Angelo, Gregory B. EOP/OMB (b) (6)>, Williams, James H. EOP/WHO (b) (6)
Overton, Heidi N. EOP/WHO (b) (6)
Cc: Steele, Danielle (OS) <Danielle.Steele@hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Follow up

Thank you Anna and team,

I know it is probably a pretty large tracker, but do you have something that lists the action FDA has taken during the PHE that is categorized in some way? Not looking for you to reinvent the wheel but assume you have something of the sort.

Looping in Heidi too.

Theo

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, June 11, 2020 6:09 PM
To: D'Angelo, Gregory B. EOP/OMB (b) (6); Williams, James H. EOP/WHO (b) (6) Merkel, Theo W. EOP/WHO <(b) (6)
Cc: Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Follow up

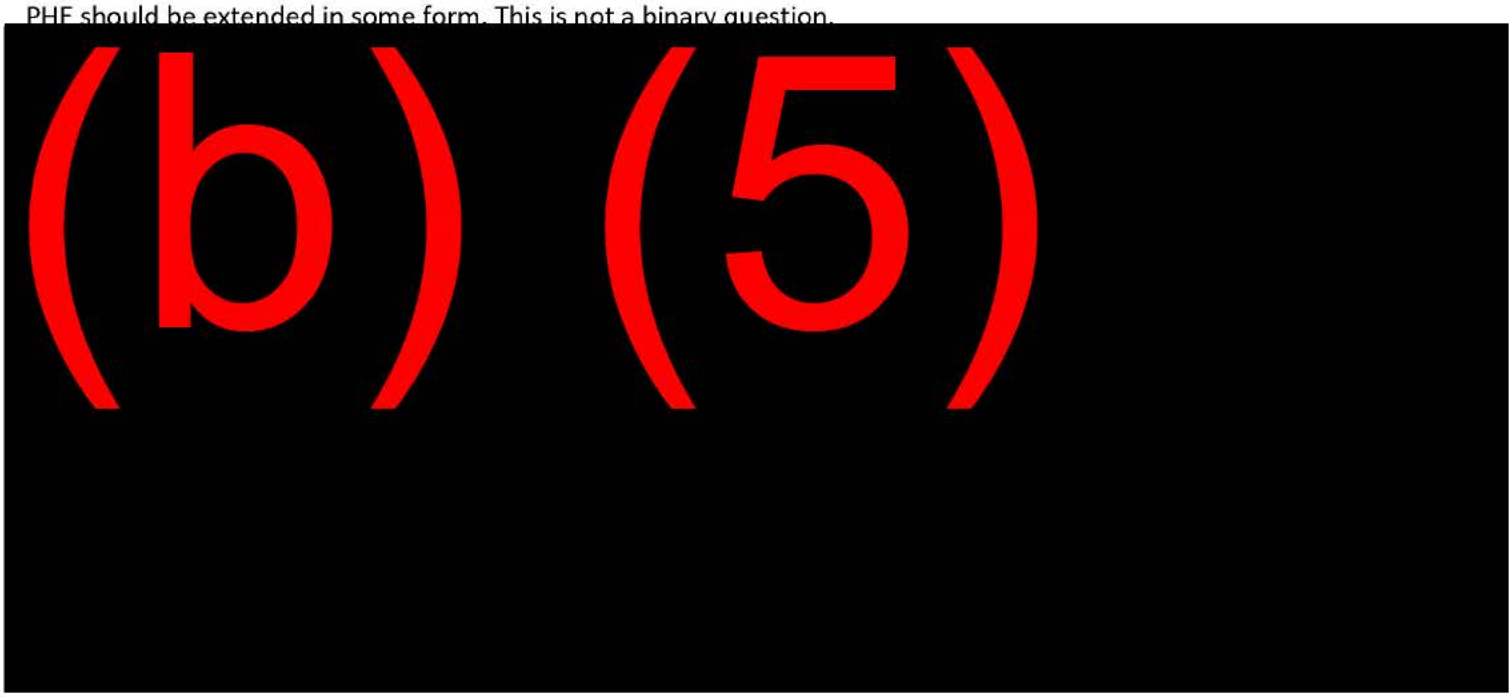
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INTERNAL CONFIDENTIAL

Greg, Theo, and James –

Hope this note finds each of you well. We understand there is an interest in an update on the Agency's work to date to implement EO 13924. We are working with the Department to provide further feedback as outlined in the OMB memorandum issued earlier this week. In the interim, below is a higher-level update with respect to the review and consideration of regs and guidances. We hope this update is helpful. Thanks!

1. FDA has already identified a number of policies issued in response to the COVID-19 public health emergency that we intend to make permanent, including:
1. COVID-19: Developing Drugs and Biological Products for Treatment or Prevention
2. Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency
3. Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products
4. Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria
5. Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry
2. For the remainder of the policies we have issued and will be issuing, we have stood up a process to evaluate each guidance in a systematic way to determine whether policies that were initially issued as expiring at the end of the PHE should be extended in some form. This is not a binary question.



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