

Subject: FW: AO v. HHS, 20-1063
Date: Monday, November 21, 2022 at 12:30:19 PM Eastern Standard Time
From: Taylor Stoneman
To: FOIA
Attachments: FDA RELEASE - Final Release in response to AO Challenges.pdf

Hi there!

Can this production please be processed as responsive to a couple different FDA FOIA numbers? These are re-releases for our case 20-1063, and the attached PDF has several PDF files within it. All but one of the files are saved with the agency tracking number 2020-1977, and are responsive to MULTI-HHS-FDA-20-0415. But the last file in the set, which is saved with agency tracking number 2020-2523, is responsive to HHS-FDA-20-0498.

Related Litigation?: 20-1063

Response Status (Interim/Final): Final

Response Type (Docs/NRR/Glomar/Rejection): Docs

Legal Reviewer: Taylor

Lead Investigator: Kelsey (formerly Narintohn)

Let me know if you have any questions!

Thanks,
Taylor

From: Powell, Amy (CIV) <Amy.Powell@usdoj.gov>
Date: Friday, November 18, 2022 at 7:09 AM
To: Taylor Stoneman <taylor.stoneman@americanoversight.org>
Subject: RE: AO v. HHS, 20-1063

Taylor:

I am attaching here another, final production from FDA, as well as a rough draft of a Vaughn index of the other requested documents.

I believe we have a JSR due today in this matter, and I will send you a draft JSR later this morning. I believe only HHS and CMS still have outstanding consults; I'm working on getting estimates. I know HHS is close to done.

Amy

Amy Elizabeth Powell
Senior Trial Counsel, Federal Programs Branch

Civil Division, Department of Justice
150 Fayetteville St, Suite 2100
Raleigh, NC 27601
Phone: 919-856-4013
Email: amy.powell@usdoj.gov

From: Taylor Stoneman <taylor.stoneman@americanoversight.org>
Sent: Wednesday, November 02, 2022 6:27 PM
To: Powell, Amy (CIV) <Amy.Powell@usdoj.gov>
Subject: [EXTERNAL] Re: AO v. HHS, 20-1063

Thanks, Amy. Just want to make sure because I'm not seeing one in the PDF—is there a cover letter associated with this production?

Best,
Taylor

Taylor Stoneman (she/her)
Counsel
American Oversight
taylor.stoneman@americanoversight.org
(202) 848-1319

From: Powell, Amy (CIV) <Amy.Powell@usdoj.gov>
Date: Monday, October 31, 2022 at 7:31 AM
To: Taylor Stoneman <taylor.stoneman@americanoversight.org>
Subject: FW: AO v. HHS, 20-1063

Please see attached from FDA. My understanding is that they still have around a dozen consults outstanding.

Amy

Amy Elizabeth Powell
Senior Trial Counsel, Federal Programs Branch
Civil Division, Department of Justice
150 Fayetteville St, Suite 2100
Raleigh, NC 27601
Phone: 919-856-4013
Email: amy.powell@usdoj.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/6/2020 5:37:22 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Finger sticks

Thanks. We wanted to make sure that we didn't run out of supply.
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 6, 2020 at 5:35:58 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Finger sticks

We used any in Africa.

Sent from my iPhone

On Apr 6, 2020, at 5:29 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

FYSA

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 3, 2020 at 1:16:36 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Finger sticks

We identified 92 firms that are manufacturers or contract manufacturers for blood lancets from information in our Registration & Listing database. Of these 92 firms, 11 are domestic and 82 are foreign. The attachment provides information on each of these firms including addresses, listing numbers, proprietary brand names and official correspondent contact information. We do not have information on production volume. These products are generally Class I, not subject to FDA review.

Please let me know if you need anything else.

From: Shuren, Jeff
Sent: Friday, April 3, 2020 7:55 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Finger sticks

All blood lancets should be usable but I'm double checking and will let you know if some can't be used. We are also pulling together a list of manufacturers from our database. The other products that will be in high demand are vacutainer tubes for venous blood draws as well as PPE.

The list below provides manufacturers of serology tests we plan to assess. All said they can currently make the amounts listed below except for Cellex who will have tests available in about (b) (4). Abbott will have lateral flow test ready for review around mid (b) (4) and automated serology around end of (b) (4) but don't have production times yet. Roche said they will give us projections late (b) (4).

Appendix A: Individual Point of Care Lateral Flow Tests

All information in the tables below is from the manufacturer and has not been reviewed by FDA.
 All manufacturers produce combined IgM and IgG lateral flow serology tests and have expressed a willingness to provide tests for independent evaluation.

Manufacturer Name	Test Name	Regulatory Authorizations	Estimated Ready to Ship to US	Estimated Weekly Production for US	Sample type
Cellex	qSARS-CoV-2 IgG/IgM Rapid Test		(b) (4)		serum, plasma
BioMedomics (through BD / Henry Schein)	COVID-19 IgM-IgG Rapid Test				fingerstick
Getein Biotech, Inc.	One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold)	CE-IVD			fingerstick, whole blood, serum, plasma
Nanjing Liming Bio-products Co.,Ltd	SARS-CoV-2 IgM/IgG Antibody Rapit Test	CE-IVD			whole blood, serum, plasma
(b) (4), (b) (5)					
Hangzhou Alltest Biotech Co.,Ltd	AllTest 2019-nCoV IgG/IgM Rapid Test Cassette AllTest COVID IgG/IgM Rapid Test Dipstick	CE-IVD, Brazil ANVISA, Guatemala Registration, Ukraine Registration	(b) (4)		fingerstick, whole blood, serum, plasma

(b) (4), (b) (5)

Manufacturer Name	Test Name	Regulatory Authorizations	Estimated Ready to Ship to US	Estimated Weekly Production for US	Sample type
(b) (4), (b) (5)					
Testsea Biotechnology	One Step SARS-CoV2 (COVID-19) IgG/IgM Test	CE Mark, DAKKS ISO13485	(b) (4)		fingerstick, whole blood, serum, plasma. The kits provide material for fingerstick.
(b) (4), (b) (5)					
Chembio Diagnostic Systems, Inc.	DPP COVID-19 IgM/IgG System	ANVISA	(b) (4)		fingerstick, whole blood, serum, plasma
(b) (4), (b) (5)					
Total			(b) (5)		

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, April 3, 2020 7:29 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Finger sticks

Thank you
 Does anyone have the firm info on IgM IgG time course?
 And I assume we (b) (5)

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, April 3, 2020 7:26 AM