U.S. FOOD & DRUG ADMINISTRATION

FDA Resources for Reproductive HCT/Ps

Marla Cassidy
Consumer Safety Officer, Division 1
Office of Biological Products Operations
Office of Medical Products & Tobacco Operations
Office of Regulatory Affairs

September 29, 2020

Objectives

- Helpful Websites
  - Navigating the FDA website
- How to access Guidance Documents
  - Review a list of helpful guidance documents and the HCT/P compliance program
- FDA Email List and how to join and receive updates

Abbreviations

- **HCT/Ps** – Human cell, tissues, and cellular and tissue-based products
- **CBER** – Center for Biologics Evaluation and Research
- **CFR** – Code of Federal Regulations

U.S. FOOD & DRUG ADMINISTRATION

Helpful Websites on www.fda.gov

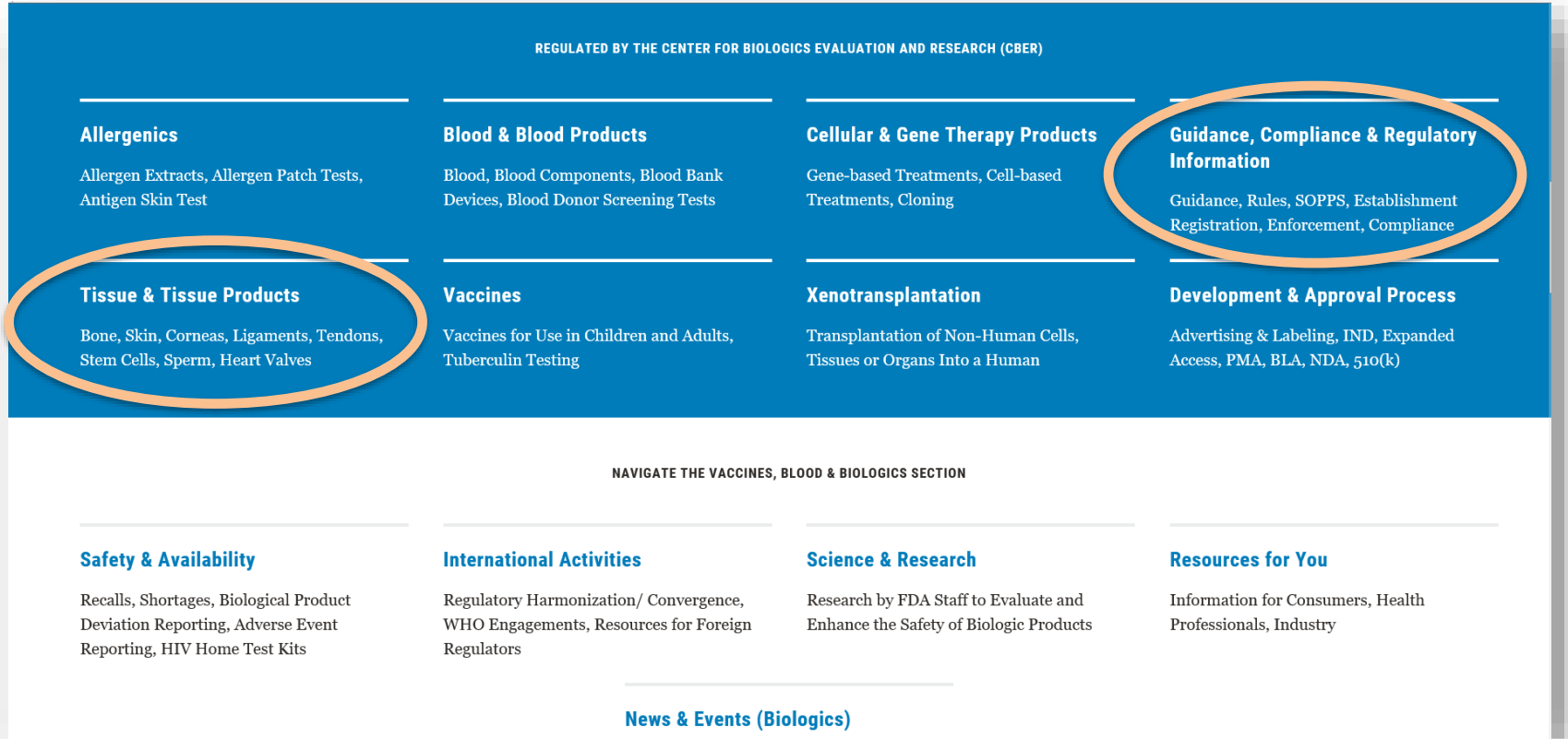
Main Page

PRODUCTS WE REGULATE

Food	Drugs	Medical Devices	Radiation-Emitting Products
Vaccines, Blood, and Biologics	Animal and Veterinary	Cosmetics	Tobacco Products

FEATURED TOPICS

Vaccines, Blood & Biologics Page



Vaccines, Blood & Biologics Page (Continued)

RECENTLY PUBLISHED BIOLOGICS-RELATED GUIDANCES

MAR 27

Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry

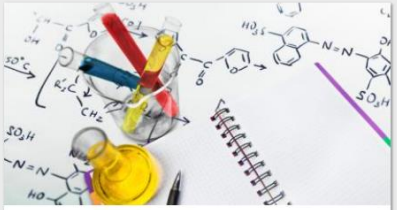
MAR 22

Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency Guidance for Industry and Health Care Professionals

MAR 19

Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic

FDA Guidance Search



Products & Establishments

Recalls

Advisory Committees

Vaccines, Blood & Biologics Page (Continued)

STAY CONNECTED

What's New for Biologics

Latest news from the Center for Biologics and Evaluation at FDA.

Follow CBER on Twitter

CBER's main goal for Twitter is to provide up-to-date information to consumers, health professionals, regulated industry and other interested stakeholders about CBER regulated products.

Workshops, Meetings & Conferences

FDA's Center for Biologics Evaluation and Research (CBER) sponsors or co-sponsors meetings, conferences and workshops about various biologics in order to educate the public and seek the opinion of interested parties.

CONTACT US

Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave WO71-3128
Silver Spring, MD 20993-0002

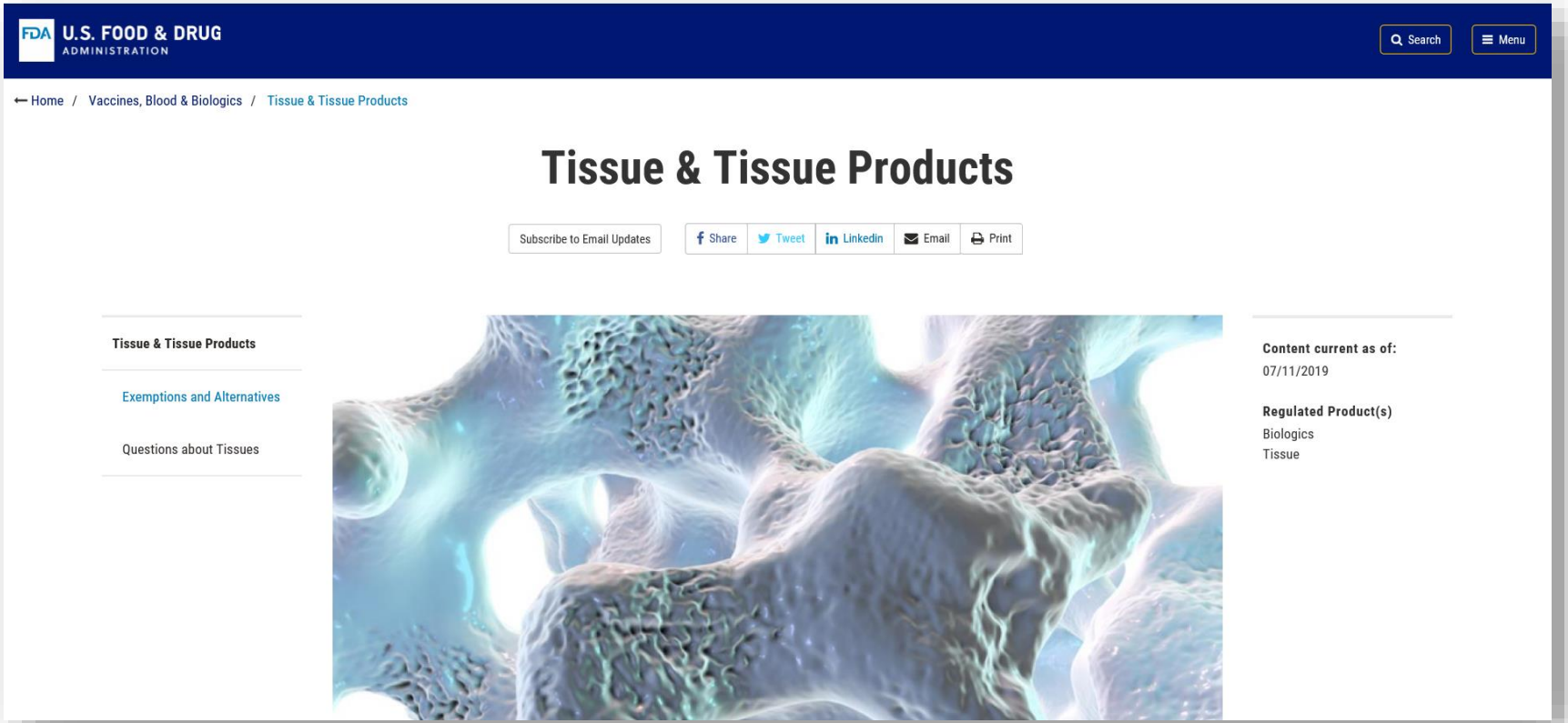
ocod@fda.hhs.gov

(800) 835-4709
(240) 402-8010

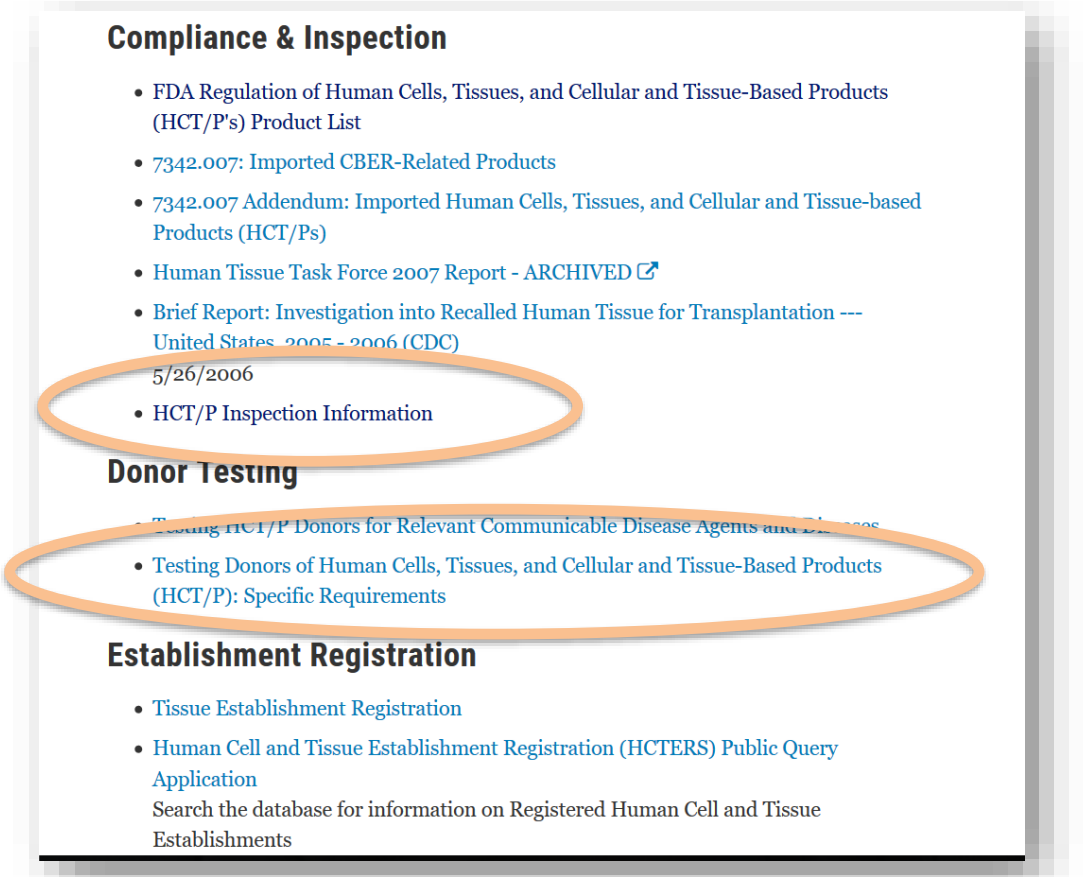
Food and Drug Administration
Food and Drug Administration
White Oak Campus
10903 New Hampshire Ave

Vaccines, Blood & Biologics Page (Continued)

Tissue and Tissue Products Page



Tissue and Tissue Products Page (Continued)



Compliance & Inspection

- FDA Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) Product List
- 7342.007: Imported CBER-Related Products
- 7342.007 Addendum: Imported Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)
- Human Tissue Task Force 2007 Report - ARCHIVED
- Brief Report: Investigation into Recalled Human Tissue for Transplantation --- United States, 2005 - 2006 (CDC)
  5/26/2006
- HCT/P Inspection Information

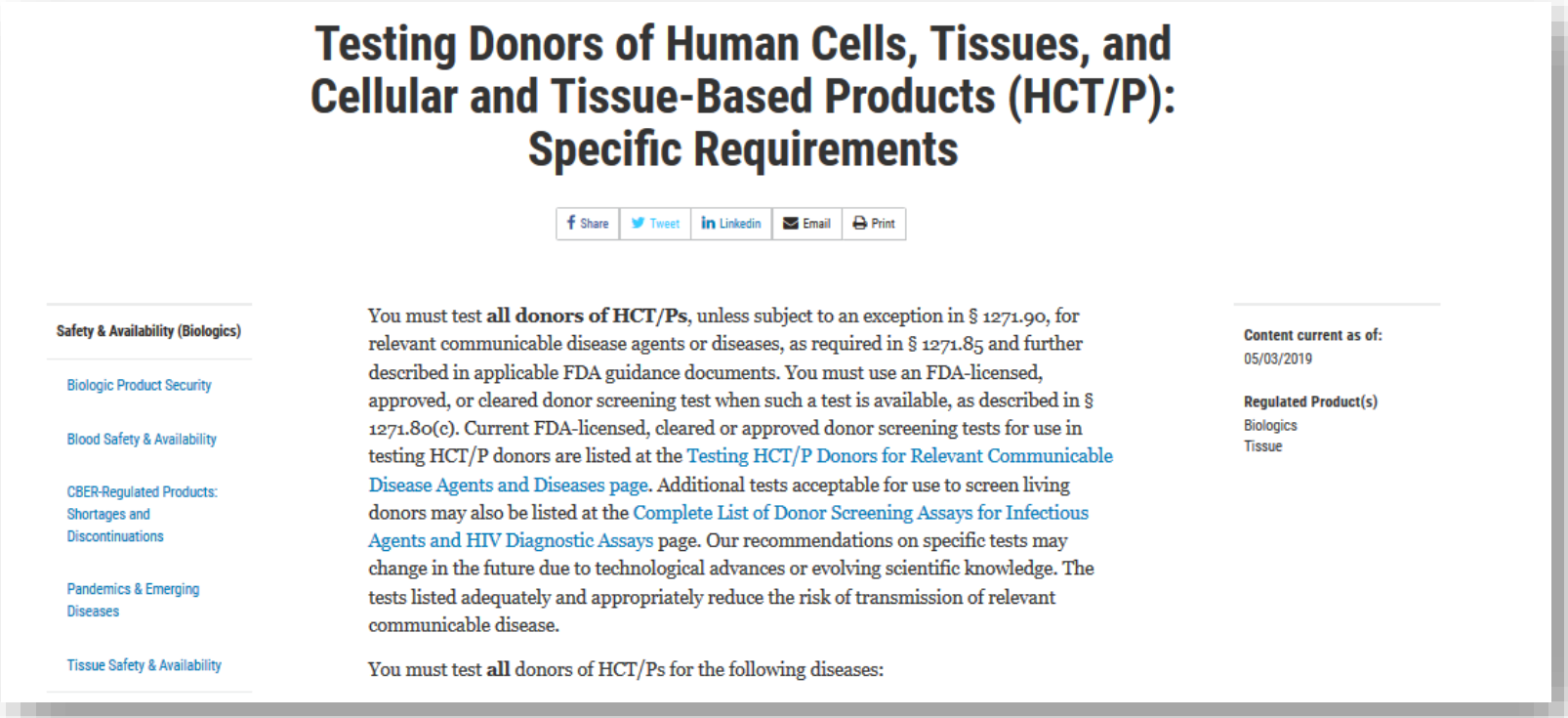
Donor Testing

- Testing HCT/P Donors for Relevant Communicable Disease Agents and Di...
- Testing Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P): Specific Requirements

Establishment Registration

- Tissue Establishment Registration
- Human Cell and Tissue Establishment Registration (HCTERS) Public Query Application
  Search the database for information on Registered Human Cell and Tissue Establishments

Testing Donors of HCT/Ps: Specific Requirements Page



Testing Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P): Specific Requirements

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Safety & Availability (Biologics)

- Biologic Product Security
- Blood Safety & Availability
- CBER-Regulated Products: Shortages and Discontinuations
- Pandemics & Emerging Diseases
- Tissue Safety & Availability

You must test **all donors of HCT/Ps**, unless subject to an exception in § 1271.90, for relevant communicable disease agents or diseases, as required in § 1271.85 and further described in applicable FDA guidance documents. You must use an FDA-licensed, approved, or cleared donor screening test when such a test is available, as described in § 1271.80(c). Current FDA-licensed, cleared or approved donor screening tests for use in testing HCT/P donors are listed at the Testing HCT/P Donors for Relevant Communicable Disease Agents and Diseases page. Additional tests acceptable for use to screen living donors may also be listed at the Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays page. Our recommendations on specific tests may change in the future due to technological advances or evolving scientific knowledge. The tests listed adequately and appropriately reduce the risk of transmission of relevant communicable disease.

You must test **all** donors of HCT/Ps for the following diseases:

Content current as of:
05/03/2019

Regulated Product(s)
Biologics
Tissue

Testing Donors of HCT/Ps: Specific Requirements Page (Continued)

You must test **all** donors of HCT/Ps for the following diseases:

1. **HIV, type 1** using an FDA-licensed donor screening test either for anti-HIV-1 or combination test for anti-HIV-1 and anti-HIV-2; and FDA-licensed donor screening NAT assay for HIV-1, or combination NAT that includes HIV-1 (establishments not utilizing an FDA-licensed donor screening test that tests for group O antibodies must screen donors for risk associated with HIV group O infection);
2. **HIV, type 2** using an FDA-licensed donor screening test either for anti-HIV-2 or combination test for anti-HIV-1 and anti-HIV-2;
3. **HBV** using an FDA-licensed donor screening test for Hepatitis B surface antigen (HBsAg); FDA-licensed donor screening test for total antibody to Hepatitis B core antigen (anti-HBc)(IgG and IgM); and FDA-licensed donor screening NAT assay for HBV, or combination NAT that includes HBV;
4. **HCV** using an FDA-licensed donor screening test for anti-HCV; and FDA-licensed donor screening NAT assay for HCV, or combination NAT that includes HCV; and
5. ***Treponema pallidum*** using an FDA-cleared donor screening test for syphilis.

For **living** donors of HCT/Ps, you must **also** test for the following diseases:

1. **WNV** using an FDA-licensed donor screening NAT assay for WNV.

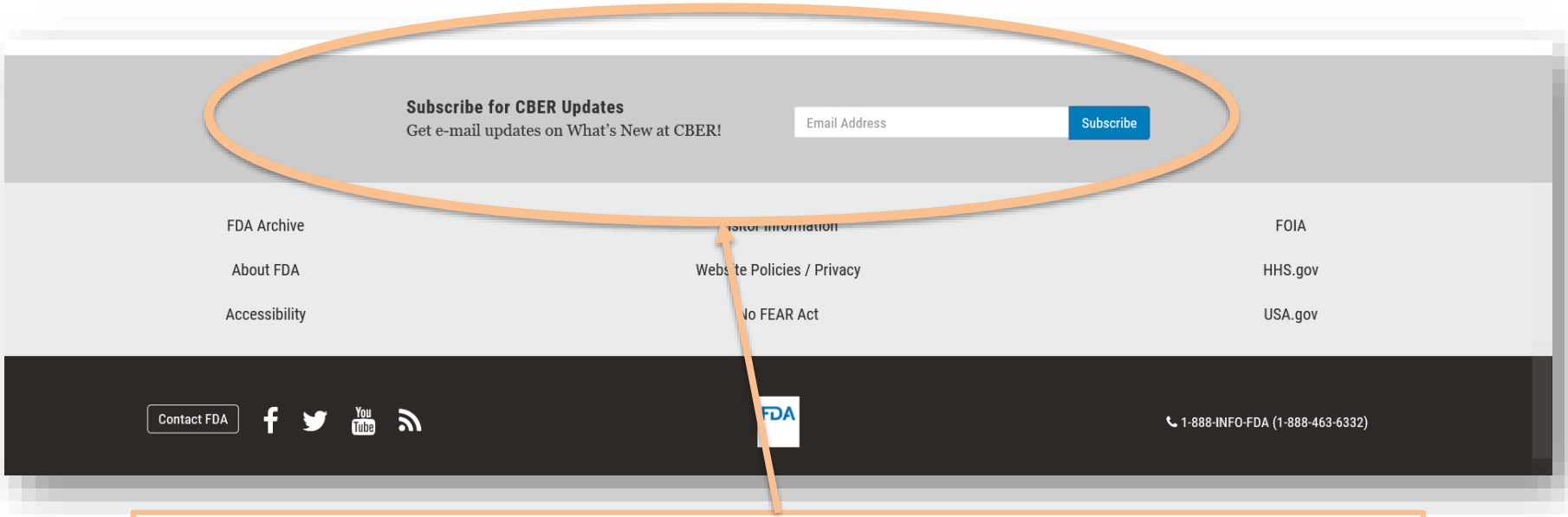
For donors of **viable, leukocyte-rich HCT/Ps**, you must **also** test for the following diseases:

1. **Human T-lymphotropic virus, types I and II** using an FDA-licensed donor screening test for anti-HTLV I/II; and
2. **Cytomegalovirus** using an FDA-cleared donor screening test for anti-CMV (total IgG and IgM).

For donors of **reproductive HCT/Ps** (unless excepted in § 1271.90), you must **also** test for the following diseases:

1. ***Chlamydia trachomatis*** using an FDA-licensed, approved, or cleared test labeled for the detection of those organisms in an asymptomatic, low-prevalence population; and
2. ***Neisseria gonorrhea*** using an FDA-licensed, approved, or cleared test labeled for the detection of those organisms in an asymptomatic, low-prevalence population.

Tissue and Tissue Products Page - Subscribe



At the bottom of the page you will see where you can subscribe to "What's New at CBER" email list.

“What’s New at CBER” Email Example

UF

Fri 3/27/2020 5:33 PM

U.S. Food and Drug Administration <fda@info.fda.gov>

What's New for Biologics

To Cassidy, Marla

If there are problems with how this message is displayed, click here to view it in a web browser.

If your email program has trouble displaying this email, view it as a web page.

FDA U.S. FOOD & DRUG ADMINISTRATION

What's New at CBER

You are subscribed to What's New at CBER for the U.S. Food & Drug Administration (FDA)
This following links have been updated recently:

Posted: 3/27/2020

- Letter to Sponsors, Applicants and Regulated Entities on COVID-19
- Summary of FDA & EMA Global Regulators Meeting on Data Requirements Supporting First-in-Human Clinical Trials with SARS-CoV-2 Vaccines

U.S. Food and Drug Administration
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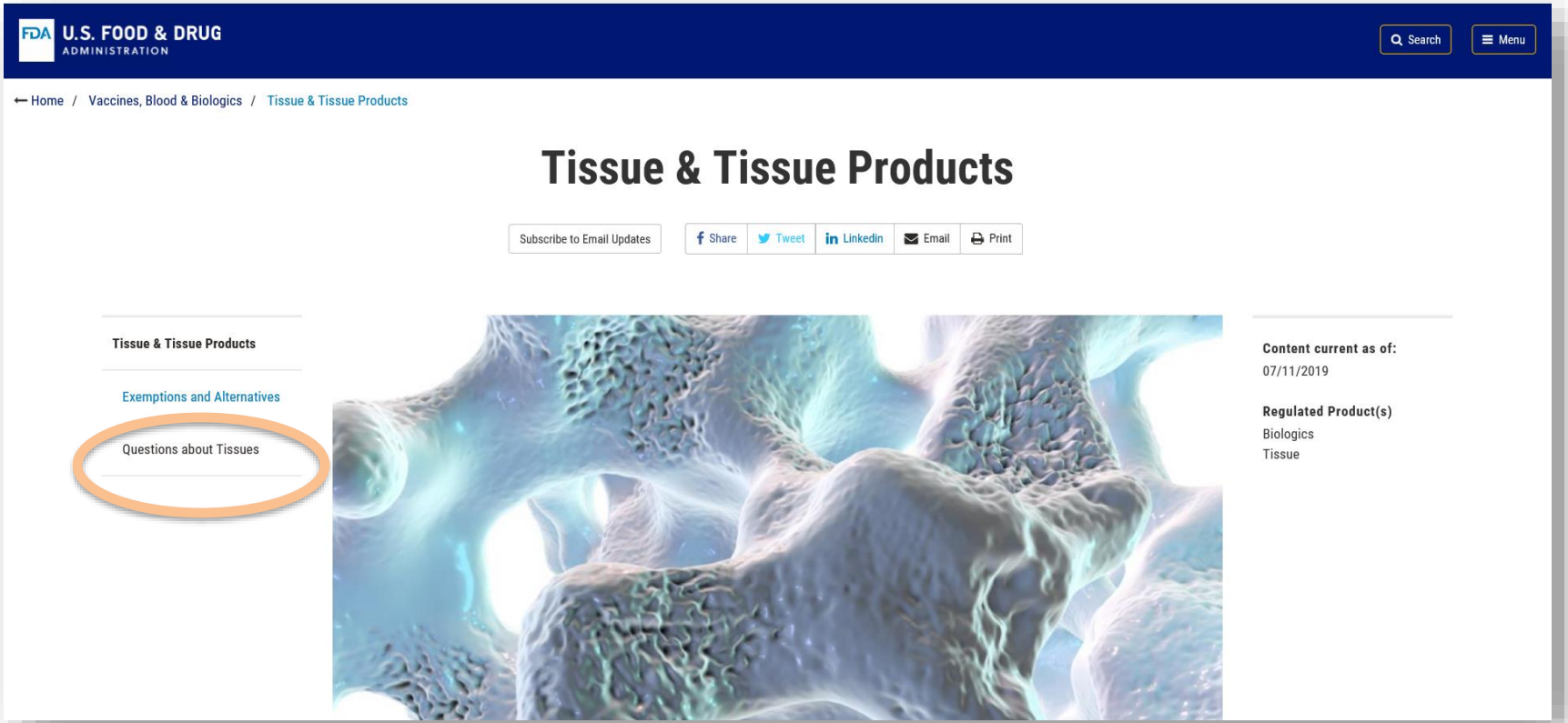
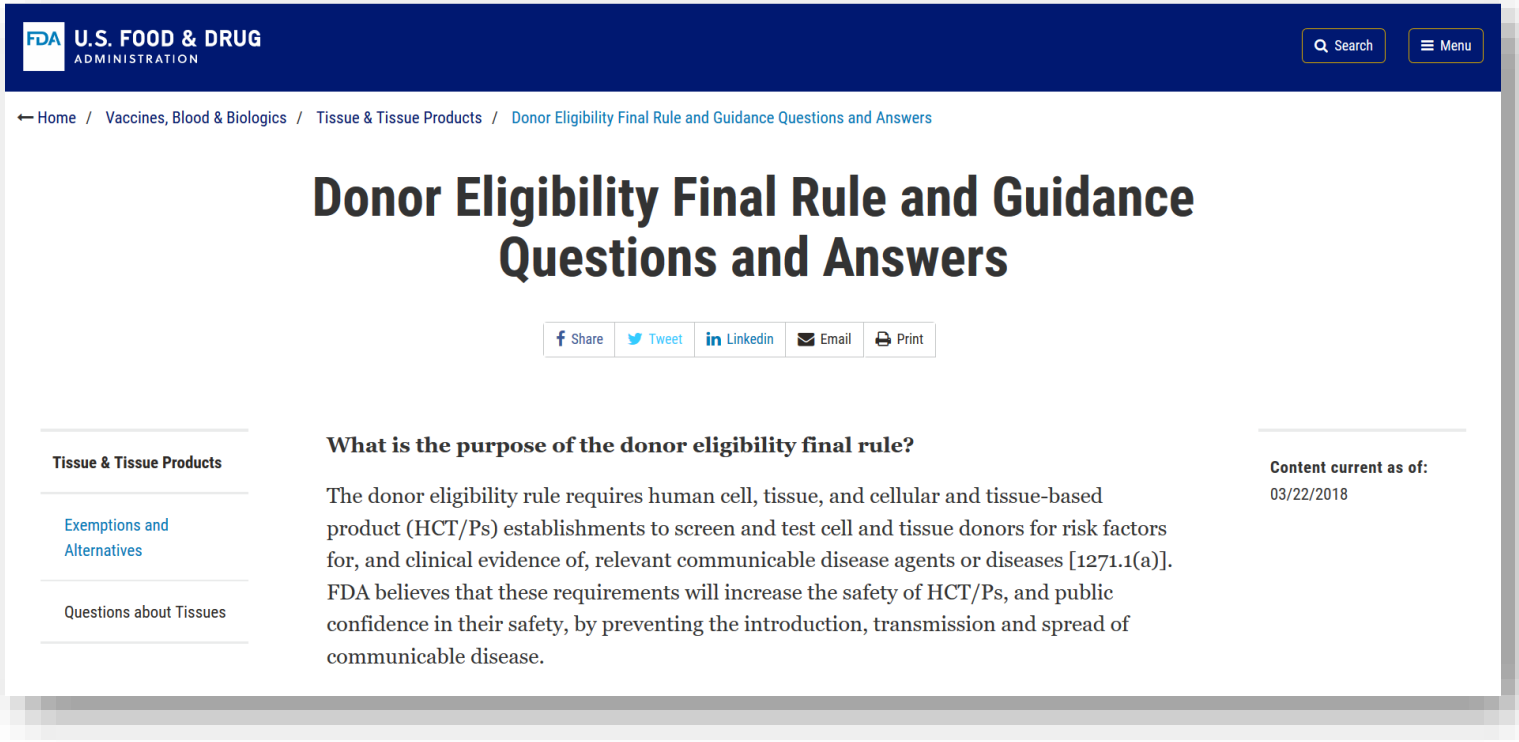
Tissue and Tissue Products Page - Questions



Donor Eligibility Final Rule and Guidance Questions and Answers Page



Donor Eligibility Final Rule and Guidance Questions and Answers Page (Continued)

Reproductive Cells and Tissues

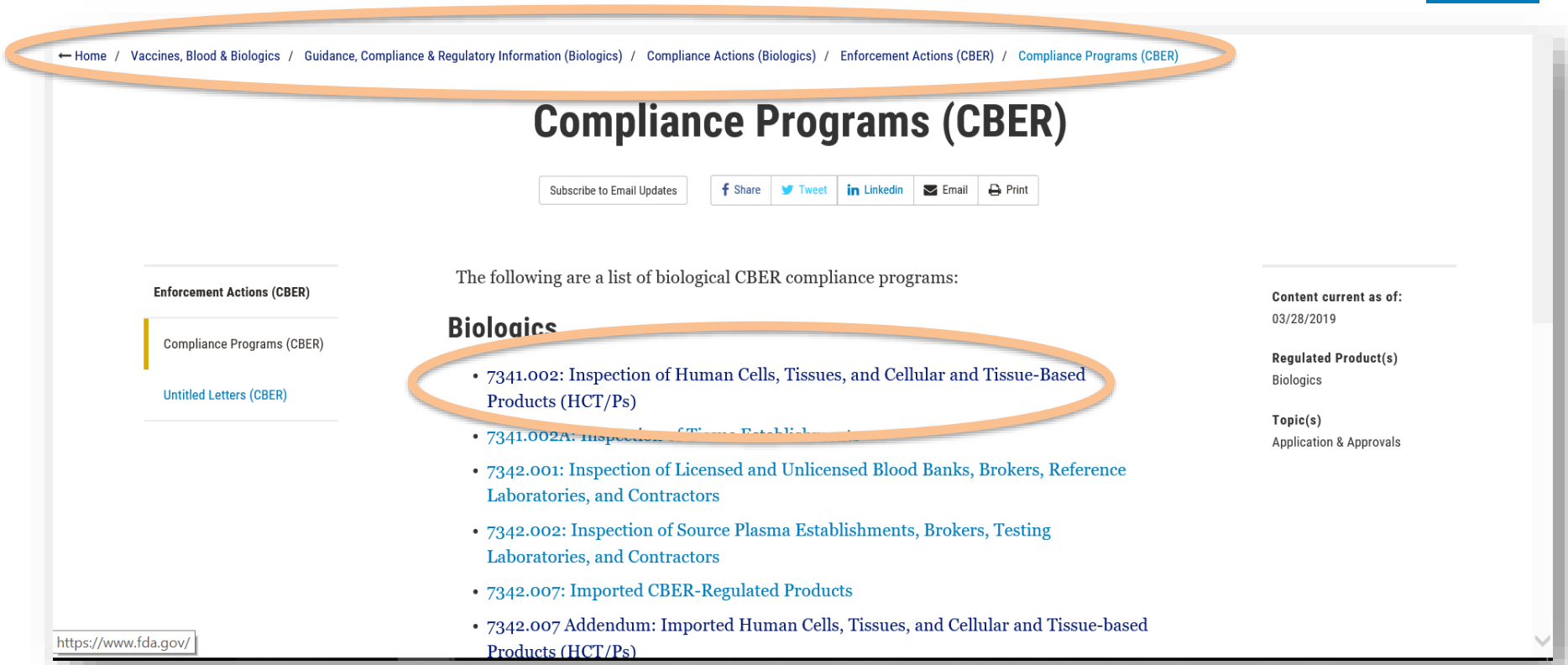
What specific exceptions are included in the regulations for donors of reproductive cells and tissues?

- A six-month quarantine for donations and retesting of directed semen donors is not required [1271.85(d)].
- The use of reproductive cells and tissue from directed donors determined to be ineligible is not prohibited [1271.65(b)(ii)].
- Donors who are sexually intimate partners are not required to be screened or tested [1271.90(a)(2)].
- Testing and screening of sexually intimate partners who later decide to donate embryos is not required; however, when possible, appropriate measures should be taken to screen and test the semen and oocyte donors before transfer of the embryos to a recipient [1271.90(a)(4)].
- Under certain circumstances, cryopreserved reproductive cells and tissue, other than embryos, can be used for directed donation, even if the donor(s) were not screened and tested initially, provided that appropriate measures are taken to screen and test the donor(s) before transfer to the recipient [1271.90(a)(3)].
- For anonymous semen donors who make repeated donations, you may perform an abbreviated history [1271.75(e)], and you are not required to collect and test a blood specimen at each donation, provided that complete donor screening and testing is

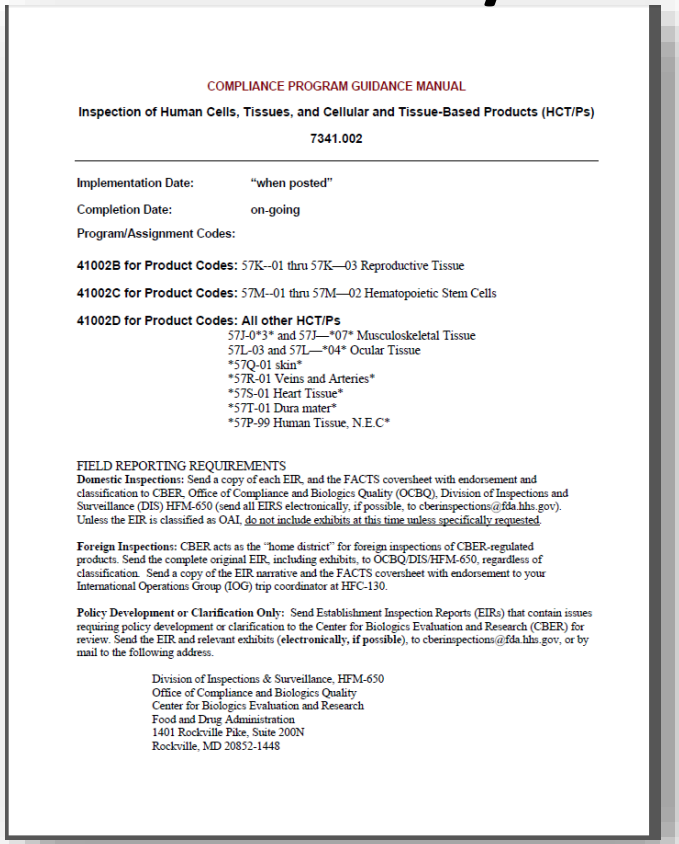
Compliance Program Guidance Manual on www.fda.gov

Vaccines, Blood & Biologics Page

Compliance Program



Compliance Program Guidance Manual
Inspection of HCT/Ps



COMPLIANCE PROGRAM GUIDANCE MANUAL

Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

7341.002

Implementation Date: "when posted"

Completion Date: on-going

Program/Assignment Codes:

41002B for Product Codes: 57K--01 thru 57K—03 Reproductive Tissue

41002C for Product Codes: 57M--01 thru 57M—02 Hematopoietic Stem Cells

41002D for Product Codes: All other HCT/Ps
57J-0*3* and 57J—*07* Musculoskeletal Tissue
57L-03 and 57L—*04* Ocular Tissue
57Q-01 skin
57R-01 Veins and Arteries
57S-01 Heart Tissue
57T-01 Dura mater
57P-99 Human Tissue, N.E.C

FIELD REPORTING REQUIREMENTS
Domestic Inspections: Send a copy of each EIR, and the FACTS coversheet with endorsement and classification to CBER, Office of Compliance and Biologics Quality (OCBQ), Division of Inspections and Surveillance (DIS) HFM-650 (send all EIRS electronically, if possible, to cberinspections@fda.hhs.gov). Unless the EIR is classified as OAI, do not include exhibits at this time unless specifically requested.

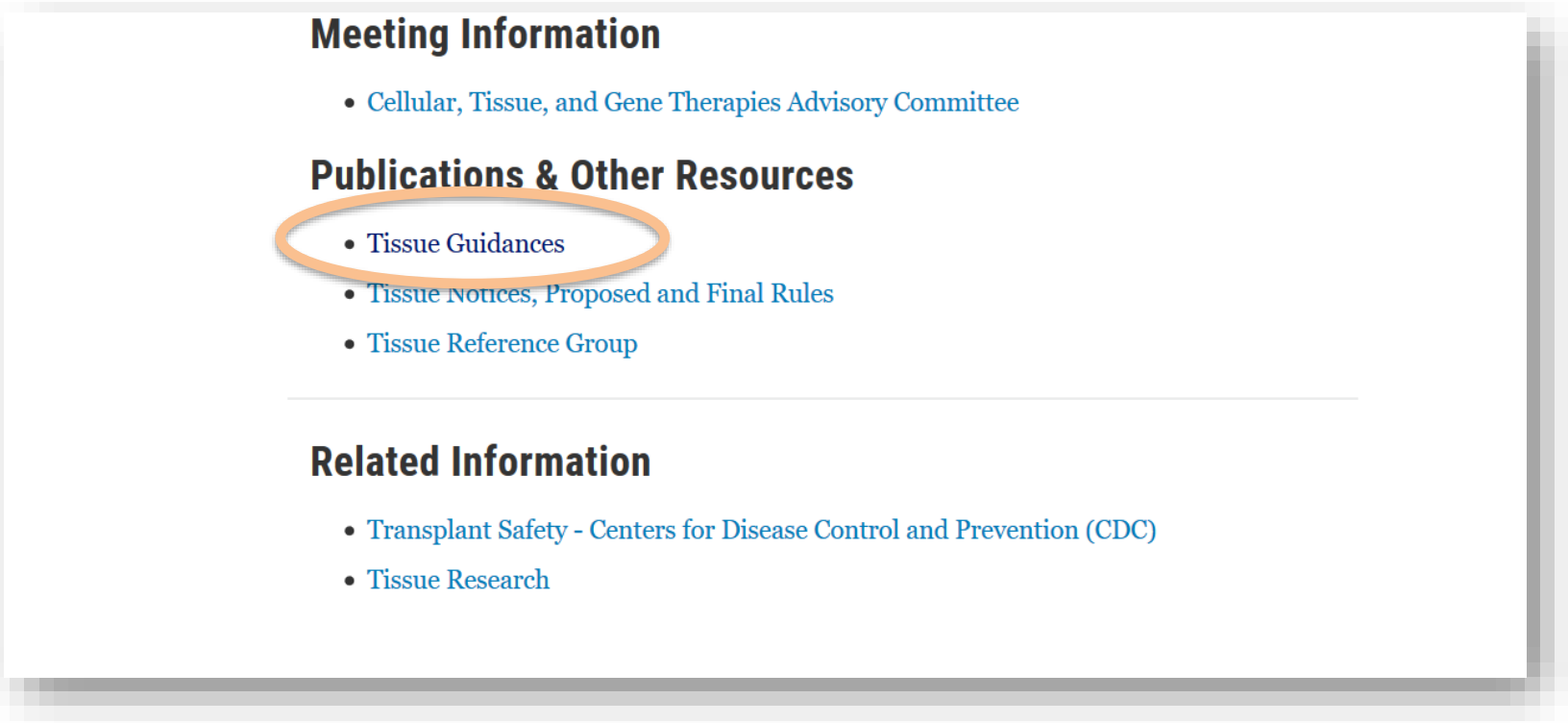
Foreign Inspections: CBER acts as the "home district" for foreign inspections of CBER-regulated products. Send the complete original EIR, including exhibits, to OCBQ/DIS/HFM-650, regardless of classification. Send a copy of the EIR narrative and the FACTS coversheet with endorsement to your International Operations Group (IOG) trip coordinator at HFC-130.

Policy Development or Clarification Only: Send Establishment Inspection Reports (EIRs) that contain issues requiring policy development or clarification to the Center for Biologics Evaluation and Research (CBER) for review. Send the EIR and relevant exhibits (**electronically, if possible**), to cberinspections@fda.hhs.gov, or by mail to the following address.

Division of Inspections & Surveillance, HFM-650
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448

Guidance Documents on www.fda.gov

Tissue and Tissue Products Page



Meeting Information

- Cellular, Tissue, and Gene Therapies Advisory Committee

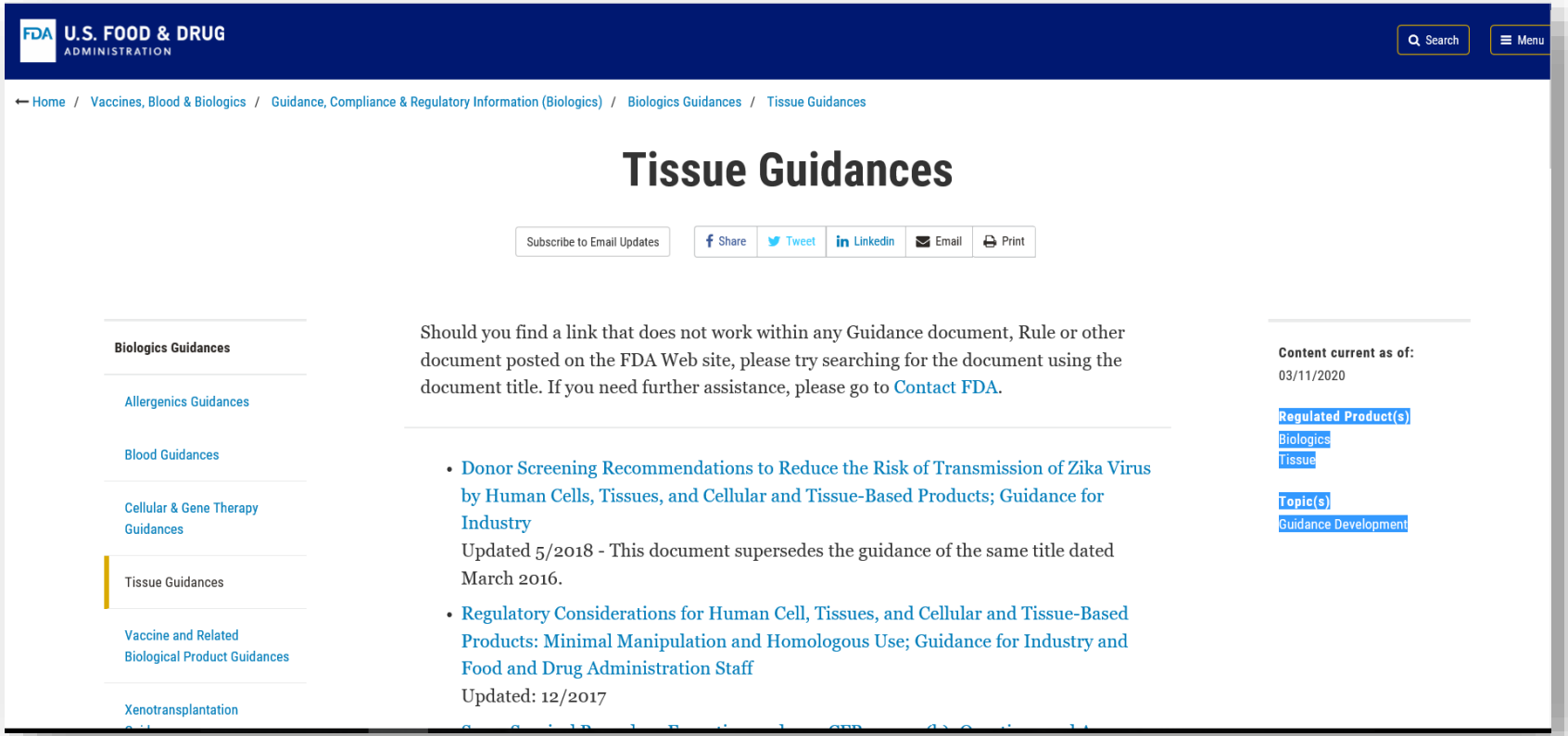
Publications & Other Resources

- Tissue Guidances
- Tissue Notices, Proposed and Final Rules
- Tissue Reference Group

Related Information

- Transplant Safety - Centers for Disease Control and Prevention (CDC)
- Tissue Research

Guidance Documents



U.S. FOOD & DRUG ADMINISTRATION

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Tissue Guidances

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Biologics Guidances

- Allergenics Guidances
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- Cellular & Gene Therapy Guidances
- Tissue Guidances
- Vaccine and Related Biological Product Guidances
- Xenotransplantation

Should you find a link that does not work within any Guidance document, Rule or other document posted on the FDA Web site, please try searching for the document using the document title. If you need further assistance, please go to Contact FDA.

- Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry
  Updated 5/2018 - This document supersedes the guidance of the same title dated March 2016.
- Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff
  Updated: 12/2017

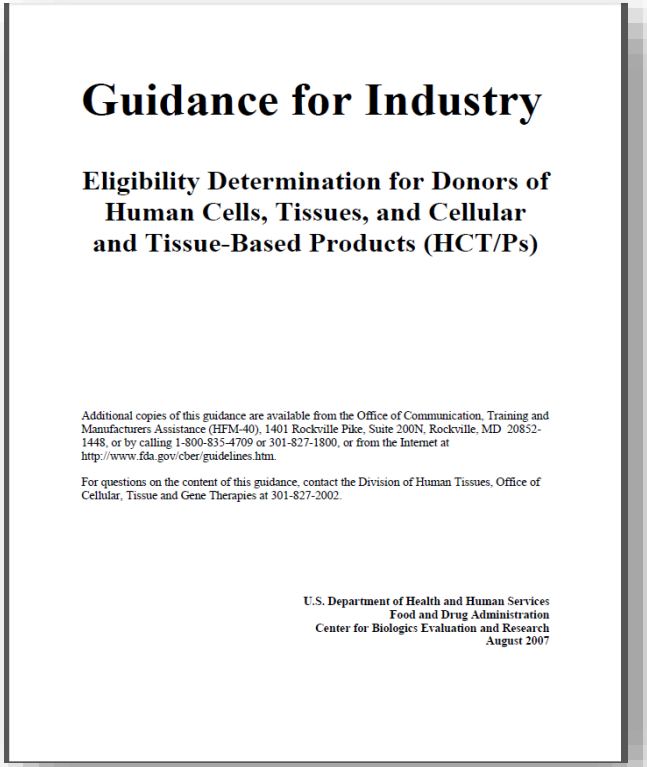
Content current as of:
03/11/2020

Regulated Product(s)
Biologics
Tissue

Topic(s)
Guidance Development

Guidance for Industry

Eligibility Determination for Donors of HCT/Ps (Dated 8/2007)



Guidance for Industry

Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

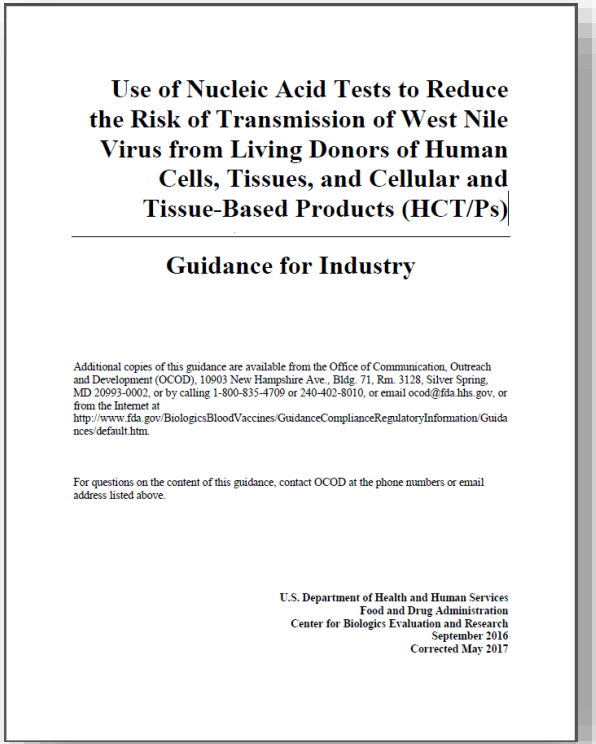
Additional copies of this guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm.

For questions on the content of this guidance, contact the Division of Human Tissues, Office of Cellular, Tissue and Gene Therapies at 301-827-2002.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
August 2007

Guidance for Industry

Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of HCT/Ps (Dated 9/2016)



Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

Guidance for Industry

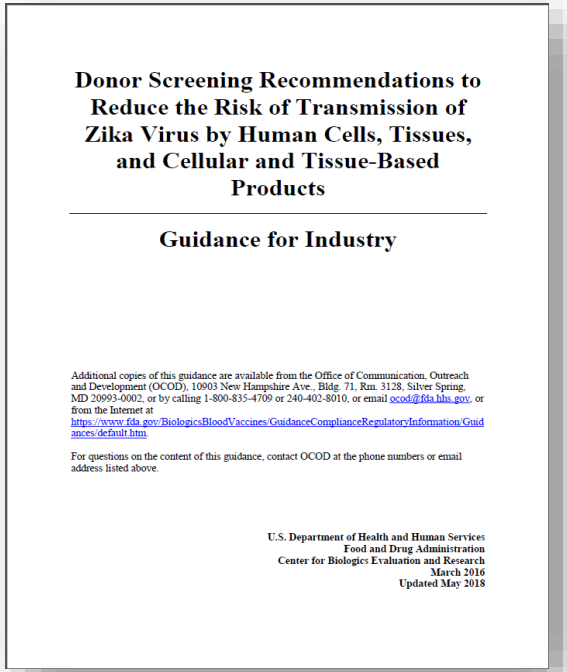
Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
September 2016
Corrected May 2017

Guidance for Industry

Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by HCT/Ps (Dated 5/2018); This document supersedes the guidance of the same title dated March 2016.



Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
March 2016
Updated May 2018

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Electronic Code of Federal Regulations e-CFR

Related Resources

The Code of Federal Regulations (CFR) annual edition is the codification of the general and permanent rules published in the FEDERAL REGISTER by the departments and agencies of the Federal Government produced by the Office of the Federal Register (OFR) and the Government Publishing Office.

Electronic Code of Federal Regulations

e-CFR data is current as of March 27, 2020

Title	Volume	Chapter	Browse Parts	Regulatory Entity
Title 21 Food and Drugs	1	I	1-99	FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
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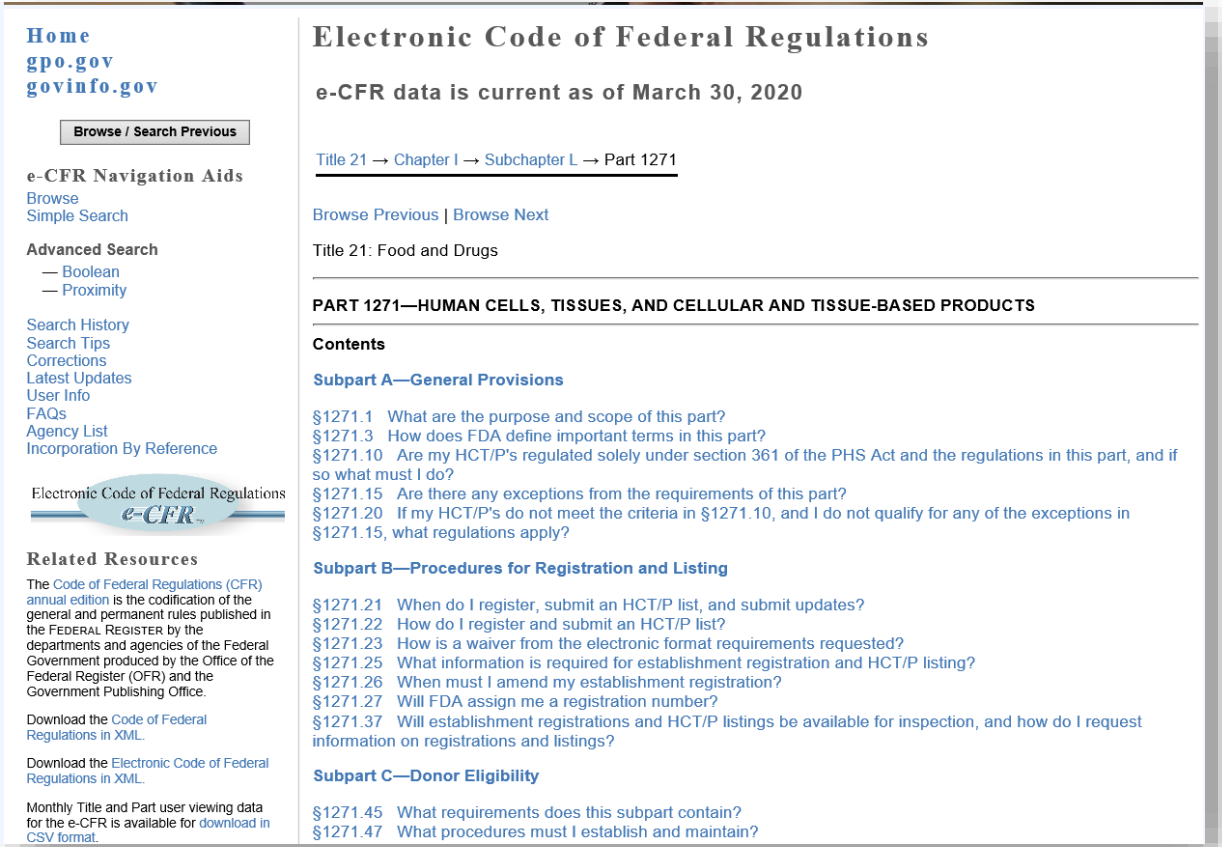
	5		300-499	
	6		500-599	
	7		600-799	
	8		800-1299	
	9	II	1300-1399	DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE
		III	1400-1499	OFFICE OF NATIONAL DRUG CONTROL POLICY

Need assistance?

eCFR Website: www.ecfr.gov



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Related Resources

The Code of Federal Regulations (CFR) annual edition is the codification of the general and permanent rules published in the FEDERAL REGISTER by the departments and agencies of the Federal Government produced by the Office of the Federal Register (OFR) and the Government Publishing Office.

Download the Code of Federal Regulations in XML.

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Monthly Title and Part user viewing data for the e-CFR is available for download in CSV format.

Electronic Code of Federal Regulations

e-CFR data is current as of March 30, 2020

Title 21 → Chapter I → Subchapter L → Part 1271

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Title 21: Food and Drugs

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

Contents

Subpart A—General Provisions

§1271.1 What are the purpose and scope of this part?
§1271.3 How does FDA define important terms in this part?
§1271.10 Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?
§1271.15 Are there any exceptions from the requirements of this part?
§1271.20 If my HCT/P's do not meet the criteria in §1271.10, and I do not qualify for any of the exceptions in §1271.15, what regulations apply?

Subpart B—Procedures for Registration and Listing

§1271.21 When do I register, submit an HCT/P list, and submit updates?
§1271.22 How do I register and submit an HCT/P list?
§1271.23 How is a waiver from the electronic format requirements requested?
§1271.25 What information is required for establishment registration and HCT/P listing?
§1271.26 When must I amend my establishment registration?
§1271.27 Will FDA assign me a registration number?
§1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

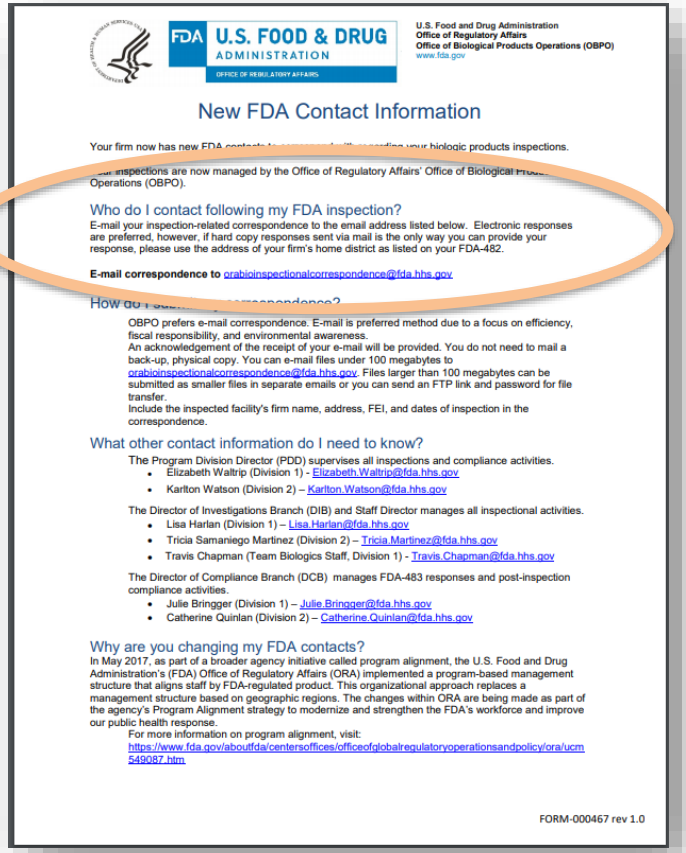
Subpart C—Donor Eligibility

§1271.45 What requirements does this subpart contain?
§1271.47 What procedures must I establish and maintain?

Email Contacts

- **Division of Manufacturers Assistance and Training, Office of Communications, Outreach, and Development (CBER)**
  - industry.biologics@fda.hhs.gov
  - Use this email address for industry questions outside of an inspection. The office tries to respond within 5 business days.
- **483 Responses Email (ORA)**
  - orabioinspectionalcorrespondence@fda.hhs.gov
  - Use this email address for responses to 483 observations after an inspection or any questions/concerns you may have regarding the inspection.

Email Contacts: FDA Inspections Handout



U.S. Food and Drug Administration
Office of Regulatory Affairs
Office of Biological Products Operations (OBPO)
www.fda.gov

New FDA Contact Information

Your firm now has new FDA contacts [illegible] regarding your biologic products inspections.

[illegible] inspections are now managed by the Office of Regulatory Affairs' Office of Biological Products Operations (OBPO).

Who do I contact following my FDA inspection?

E-mail your inspection-related correspondence to the email address listed below. Electronic responses are preferred, however, if hard copy responses sent via mail is the only way you can provide your response, please use the address of your firm's home district as listed on your FDA-482.

E-mail correspondence to orabioinspectionalcorrespondence@fda.hhs.gov

How do I [illegible] correspondence?

OBPO prefers e-mail correspondence. E-mail is preferred method due to a focus on efficiency, fiscal responsibility, and environmental awareness.
An acknowledgement of the receipt of your e-mail will be provided. You do not need to mail a back-up, physical copy. You can e-mail files under 100 megabytes to orabioinspectionalcorrespondence@fda.hhs.gov. Files larger than 100 megabytes can be submitted as smaller files in separate emails or you can send an FTP link and password for file transfer.
Include the inspected facility's firm name, address, FEI, and dates of inspection in the correspondence.

What other contact information do I need to know?

The Program Division Director (PDD) supervises all inspections and compliance activities.

- Elizabeth Waltrip (Division 1) - Elizabeth.Waltrip@fda.hhs.gov
- Karlton Watson (Division 2) – Karlton.Watson@fda.hhs.gov

The Director of Investigations Branch (DIB) and Staff Director manages all inspectional activities.

- Lisa Harlan (Division 1) – Lisa.Harlan@fda.hhs.gov
- Tricia Samaniego Martinez (Division 2) – Tricia.Martinez@fda.hhs.gov
- Travis Chapman (Team Biologics Staff, Division 1) - Travis.Chapman@fda.hhs.gov

The Director of Compliance Branch (DCB) manages FDA-483 responses and post-inspection compliance activities.

- Julie Bringger (Division 1) – Julie.Bringger@fda.hhs.gov
- Catherine Quinlan (Division 2) – Catherine.Quinlan@fda.hhs.gov

Why are you changing my FDA contacts?

In May 2017, as part of a broader agency initiative called program alignment, the U.S. Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) implemented a program-based management structure that aligns staff by FDA-regulated product. This organizational approach replaces a management structure based on geographic regions. The changes within ORA are being made as part of the agency's Program Alignment strategy to modernize and strengthen the FDA's workforce and improve our public health response.
For more information on program alignment, visit:
https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/ucm549087.htm

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