Introduction to Biologics and Biosimilars Law and Regulation

Violations, Enforcement, and International Issues

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FDLI

Agenda

- Interstate Commerce Element
- Prohibited Acts
- Enforcement Tools and Procedures
- Prevention Tactics
- International Harmonization
- Imports
- Exports

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Interstate Commerce Element

Interstate Commerce Element

- "The introduction or delivery for introduction into **interstate commerce** of any food, drug, device, or cosmetic that is adulterated or misbranded" (21 U.S.C. § 331(a))
- "The adulteration or misbranding of any food, drug, device or cosmetic in **interstate commerce**" (21 U.S.C. § 331(b))
- "The receipt in **interstate commerce** of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise" (21 U.S.C. § 331(c))
- "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in **interstate commerce** and results in such article being adulterated or misbranded" (21 U.S.C. § 331(k))

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Interstate Commerce Element (cont'd)

Manufactures, packers, distributors, and retailers all are involved in interstate commerce and are responsible to assure products are not adulterated or misbranded (even if someone else causes this earlier in the chain) and applies to components and packaging too

- Circumstances that place a product in interstate commerce:

  "(1) commerce between any State or Territory and any place outside thereof, and
  (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body." (21 U.S.C. § 321(b)).

- Some exceptions where all ingredients/packaging stay in state but not frequently the case

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Prohibited Acts

Prohibited Acts

- Most common – adulterated or misbranded
- Strict liability, i.e., based on evidence of violation
- Committing or causing acts/violations
  - "Causing" no statutory definition but broadly interpreted – includes aiding and abetting, inducement of illegal activity, and willful ignorance of illegal acts.
- Some of the 40+ prohibited acts (21 U.S.C. § 331) are criminal acts under other statutes, e.g., mail/wire fraud, false statements, conspiracy

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Prohibited Acts (cont'd)

- Adulteration
  - Manufacturing defects including recordkeeping
    - Fails to conform to compendial standards of quality, strength, or purity
    - Deviates from cGMPs e.g., unsanitary conditions
    - Refusal to permit inspections
  - Marketing uncleared/approved products.

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Prohibited Acts (cont'd)

- Misbranding
  - "False or misleading" product labeling or advertising – "off-label" promotion" (intended use and adequate directions for use)?
  - Absence of required information in labeling e.g., statements of identity, source, ingredients, or quality
  - Requirement violation, e.g., registration, adverse event reporting.

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Prohibited Acts (cont'd)

- Corporate officers may be held vicariously liable for violations of the company
  - *U.S. v. Park*, 421 U.S. 658 (1958)
    - Yates Memo (9/9/2015) re-invigored this approach.
- But FDA may exercise "enforcement discretion" by declining to enforce certain provisions of that statute
  - *Heckler v. Chaney*, 470 U.S. 821 (1985).
- And courts may provide "equitable remedies"
  - *U.S. v. Lane Labs-USA, Inc.*, 427 F.3d 219 (3d Cir. 2005).

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Enforcement Tools and Procedures

Inspections

- FDA credentials and FDA Form 482 (Notice of Inspection) of factory, warehouse, establishment where product manufactured, processed, packed, or stored for introduction into interstate commerce w/o warrant
- Limited to reasonable times, within reasonable limits, and in reasonable manner
- “Reasonable” includes
  - Required records, vehicles/containers on property, manufacturing equipment, complaint/adverse event files, labeling
  - DOES NOT INCLUDE – internal audits (FDA discretion), personnel information, and sales data.

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Inspections (cont'd)

- Types include pre-approval, routine, and for-cause
- For-cause may be triggered by retail purchase, undercover observation, and Internet purchase/monitoring
- Higher-risk products undergo more in-depth quality and cGMP evaluations

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Inspections (cont'd)

- Preparation
  - Develop an inspectional plan with specific manager
  - SOPs are critical – as well as training of SOPs
  - Escort investigator at all times / document activities
  - Develop process to respond to inspector requests
    - Audits, interviews, note-taking
    - Inspectional support, source documents, quality control, and ready/appropriate experts.
- AVOID
  - Documents not available, obsolete, or wrong / opinions & extra info
  - Gaps in documentation before providing
  - Confusion / disorder / unruly attitude toward inspector
  - Refusing inspector items/access that are reasonable or arguing
  - Providing the FDA sworn affidavits (not required) and photos.

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Inspections (cont'd)

- Results in Establishment Inspection Report (EIR)
- FDA Form 483 may result in regulatory action and provides list of correctable items and provides details of inspection
- During close-out meeting, begin response to 483 and ask questions and try to remove items that are inaccurate or have been corrected
- Respond to 483 w/in 15 business days but not final agency action
  - Senior management needs to address in cover letter/statement
  - Each observation repeated and addressed with specificity but do not need to admit; if dispute, use facts, evidence, and science
  - Consider if need a recall or system overall
  - Address need for internal audit & assess potential criminal activity
  - Engage consultants as independent advisors
  - Focus on root cause and Corrective and Protective Actions (CAPAs) and SOPs along with appropriate documentation and verify correction worked with clear timelines.

Inspections (cont'd)

- Other types of inspections
  - Clinical investigations may also be inspected
    - Sponsors, clinical investigator, or IRBs may have misconduct, including falsification of data, errors in adverse event reporting, protocol violations, lack of informed consent or IRB approval, poor records/monitoring, and other compliance issues
    - EIR and FDA Form 483 issued, which may lead to Notice of Intent to Disqualify Proceedings and Opportunity to Explain (NIDPOE) Letters
    - More serious actions lead to Notice of Opportunity for Hearing (NOOH) and possible Disqualification (repeated or deliberate failure to follow regulations/false information) or Debarment (criminal activity by firm or person)
    - Disqualified/debarred individuals cannot be used for clinical studies but may be reinstated under restrictive and limited process.

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Inspections (cont'd)

- FDA/District categorizes EIR/483 as
  - NAI – No Action Indicated
  - VAI – Voluntary Action Indicated
  - OAI – Official Action Indicated.
- HHS/OIG may also inspect FDA programs but typically focuses on CMS-type issues
- Inspections may lead to product liability or consumer suits

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Administrative License Action Letters

- FDA/CBER may issue Notice of Intent to Revoke License and provide opportunity to demonstrate compliance prior to License Revocation Letter
  - BUT NOT required if license suspended or willful violations and reasonable grounds for revocation or danger to public health.

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Warning Letters and Untitled Letters

- Provides opportunity to take voluntary and prompt corrective action and to provide prior notice
- Warning Letters for “violations of regulatory significance” or “those violations that may lead to enforcement action if not promptly and adequately corrected” BUT DOES NOT commit enforcement action
  - FDA may take enforcement action before issuing Warning Letter
  - Still an “informal and advisory” process
  - Public document – usually posted within 2 weeks from issuance.
- Untitled Letters have less regulatory significance to the FDA
  - FDA does not inform other agencies
  - Lacks warning that failure to take prompt corrective action may result in enforcement action
  - Typically no mandated follow-up action
  - Longer response time, e.g., 30 days versus 15 working days

Warning Letters and Untitled Letters (cont'd)

- Factors considered
  - Significance/perception of violations
  - Compliance history / repeat violation?
  - Company awareness of problem and observed intent to correct/CAPA and speed to correct
  - Possible precedent setting objective
  - May be issued by District but may involve Center or OCC review.
- Elements include
  - Citations to violations of law / regulations
  - May include observations / 483 and responses
  - Impact for failure to correct, e.g., federal contracts, import/export.

Warning Letters and Untitled Letters (cont'd)

- Responses should include
  - Each violation must be addressed with specificity and sustainable fixes, including any gaps or delays in resolution and why
  - Analysis of root cause analysis and CAPAs in detail with documentation and timelines
  - May request meeting with the FDA to explain / work out solution
  - Identify and mark proprietary documents/references
  - Senior official with authority to fix situation should respond.
- Close-out Letter or reinspection without same violations noted
  - May be posted on Warning Letter page as closed out
  - Public through FOIA once closed out, so consider redaction strategy for trade secret and commercial/confidential information or information that may interfere with enforcement proceedings.

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Use of Media/Publicity

- Statements which invite public attention and which may adversely affect individuals identified therein
- One of the few federal agencies in government that is specifically required and authorized by law to use publicity – *see* Section 705 of the Food, Drug and Cosmetic Act (FD&C Act):
  - "Sec. 705. (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.
  - (b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department."

Use of Media/Publicity (cont'd)

- FDA, under delegation of authority of the Secretary of Health, Education and Welfare, may issue publicity under the Federal Hazardous Substances Act (15 U.S.C. § 1272) concerning products which constitute a danger to health. Section 13 of the Hazardous Substances Act is nearly identical to Section 705 of the FD&C Act. In addition, the Office of Product Safety, the division of the FDA which is charged with the enforcement of the Hazardous Substances Act, may publish in the *Federal Register*, without a prior hearing, notice that particular products constitute an imminent danger to public health and that such products are banned hazardous substances (15 U.S.C. §1261(q)(2)).
  - Under 705(a) the FDA publishes reports summarizing judgments, decrees, and orders in each case brought under the Act, e.g., "Notices of Judgment."
  - Under 705(b), however the FDA may direct publicity at specific products that, in FDA's opinion, involve "imminent danger to health" or "gross deception of the consumer."

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Use of Media/Publicity (cont'd)

- Types of actions include
  - Press releases and public announcements and warnings, formal press conferences, briefings, interviews, speeches, individual letters, and other forums
  - Published reports and announcements also appear in the *FDA Consumer*, the *FDA Enforcement Report*, the *Federal Register* and other private journals.
- Most often used in connection with product recalls
  - Manufacturer also uses to remove and notify public of products recalled and situations where products may be with consumers and cannot be recalled from product shelves
  - Manufactures may need to rebuild consumer and distributor trust
- No duty to inform company of FDA's intent to issue adverse publicity
- But how far can FDA go?

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Use of Media/Publicity (cont'd)

- *Hoxsey Cancer Clinic, Inc. v. Folsom,* l55 F. Supp. 376 (D. D.C. 1957).
  - Plaintiffs attempted to enjoin the FDA's **dissemination of posters that** warned the public that the so-called Hoxsey cancer treatment was worthless
  - At that time was most widely circulated warning issued by FDA
  - Court essentially upheld the FDA's use of publicity as constitutional, against claims that it was a denial of due process, even though it does not provide for any notice or hearing before publicity is issued
  - Suggests the FDA has an implied authority to use publicity because of the nature of its regulatory duties.

Use of Media/Publicity (cont'd)

Later cases question FDA's authority

- *U.S. v. Abbott Laboratories*, 505 F.2d (4th Cir. 1974)
  - FDA released prejudicial pre-trial publicity in the form of a PR naming Abbot Laboratories and associating fifty blood poisoning deaths with the use of Abbott's intravenous solutions, even after Abbot issued a nationwide recall two months earlier
  - Court accepted "without question, that the pretrial publicity in this case was prejudicial and highly inflammatory" but did not dismiss indictment against Abbott.
- *U.S. v. International Medication Systems Ltd., C*iv. No. 73-626-WPG (CD Cal. 1973)*, aff'd,* No. 73-3260 (9th Cir. 1974)
  - FDA requested recall and threatened to inform nation's hospitals of health threat of sterility of product; IMS refused, the FDA so notified and court denied FDA's motion for injunction, found the FDA overstepped bounds and ordered corrective publicity (latter later removed by agreement between the FDA and IMS).

Use of Media/Publicity (cont'd)

- Cranberry Scare – 1959 FDA issued warning for pesticide on cranberries during peak of cranberry sales for Thanksgiving due to high doses used in Washington and Oregon crops but only <1% nation's crop with lingering effects → unusual case because cranberry growers compensated for damaged market - $9 million.
- Options to Remedy?
  - Often risky to refute presumption of FDA's objectivity
  - Rare to obtain order for corrective publicity or private bill to correct
  - Courts hesitant to order injunction against the FDA without proof of irreparable harm and public interest to disclose often prevails
  - FDA immune under Federal Torts Claim Act for libel, slander, or misrepresentation.

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Recalls

- Consider when
  - Safety, quality, or compliance risk for product
  - Potential loss of good will with customers
  - Potential for inspection/seizure/483/warning letter/consent decree situation if not corrected
  - Labeling nonconformity including proper IFU, identity, expiration date, storage condition - or – potency, active, or nonactive ingredient list or amount error – or – error in manufacturer address, warnings/precautions, product identifier, tests per sales unit, or previously-unidentified warnings
  - Possibility to avoid if merely a device enhancement (if combination biologic/device) and not a change to remedy a violation.

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Recalls (cont'd)

- Often linked to current good manufacturing processes or CAPAs for non-conforming product or quality issues, where failure to recall could be violative under the FD&C Act
  - For biologics key health issues risks include communicable disease or infection, contamination, product deviations, and adverse event reporting and events, which may require destruction / decontamination or cessation manufacture of product.
- Includes failure to perform as intended or inadequate directions for use or implication for indications not cleared/approved or out of compliance with FD&C Act, regulations, or guidance, including revised versions
- Classified as I, II, III – if exposed to violative product …
  - I – reasonable probability product will cause serious adverse health consequence or death (more likely than not will occur)
  - II- may cause temporary or medically-reversible health consequences (remote probability serious adverse health issue)
  - III – not likely to cause adverse health consequence.

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Recalls (cont'd)

- Mandatory v. Voluntary
  - Mandatory if would cause serious, adverse health consequences or death (biologics 42 U.S.C. § 262(d); human cell and tissue products, 21 C.F.R. §§ 1270.43 and 1271.440)
    - FDA issues order to cease distribution and for the manufacturer/distributor to notify health professionals and facilities with the product
    - Opportunity for informal hearing to determine if adequate grounds for the order (w/in 10 days issuance)
    - May also specify recall timetable and require periodic reports to FDA and notification to individuals subject to risk of use
    - Rarely used.

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Recalls (cont'd)

- Mandatory v. Voluntary (cont'd)
  - Voluntary most common for manufacturers to remove products with risk of injury or gross deception, including possible user error
  - Alternative to FDA-initiated court action
  - May be undertaken at any time by manufacturer/distributor depending on primary responsibility for manufacture/marketing
  - Need to report to the FDA those with risk but may be under regular reports
  - Manufacturers and importers have to keep records for any removals not required to be reported, e.g., to improve the performance or quality or a remedy to a violation of the FD&C Act caused by the product, as well as market withdrawals, stock recoveries, and, if applicable, routine servicing (combo medical device).

Recalls (cont'd)

- "Market Withdrawal" means correction or removal of product that involves minor violation of the act that would not be subject to legal action by the FDA or involves no violation of the act, e.g., routine stock rotation practice
- "Stock Recovery" means removal or correction of a product that has not been marketed or left the direct control of the firm, i.e., still on the premises, owned by, or under control of the firm with no portion of the lot released for sale or use
- Good to establish relationships with FDA District Offices and communicate with them PRIOR to a recall to align strategy, communication content, and any issues/concerns including providing scope of recall, awareness of issue, root cause, and CAPA
  - Must inform district office within 10 working days.
- Develop post-recall surveillance plan to see recall and communication effective and possible modify quality controls and notify FDA District when done / final status

Seizure

- DOJ represents the FDA – must establish statutory violation in court
- Filed in federal court to prevent violative goods from entering commerce
- ORA conducts inspection, results in Form FDA 483 and sends company EIR and recommendations to Center
- Center reviews and forwards to ORA's Office of Enforcement (OE)
- OE reviews, drafts letter, complaint, warrant, and sends to OCC
- Action filed in federal court, carried out by U.S. Marshalls Service

Suits for Injunctions

- DOJ represents the FDA – must establish statutory violation in court
- Preliminary v. Permanent Injunctions
- Actions against individual, company, or both
- No evidence of actual injury or harm required
- Prohibitive (cannot do activity "unless or until" the FDA finds compliant)
- Mandatory (can do activity but must take specific actions by when or subject to penalties or other sanctions)
- Criteria
  - Recent violations or prior history of same conduct
  - Acts to halt required to prevent flow of violative goods in commerce
  - Health hazard / gross consumer deception requires action
  - Failure to correct pre-existing violations
  - Significant amount of product by same party in multiple locations.

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Equitable Remedies in Court

- Restitution (victims made “whole” for losses suffered)
- Disgorgement (strips “ill-gotten gains”)
- Continuous FDA oversight of operations

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Consent Decrees

- Negotiated settlement between the FDA and company/individual
- Associated with planned or filed injunction
- Standard provisions for “letter shut down” authority and liquidated damages for decree violations
- To prevent shortage, the FDA may permit continued shipment with disgorgement of profits
- May be difficult to lift permanent injunction without longer-term compliance, e.g., 5+ years of continuous compliance with oversight paid by company/individual
- Helpful to create dedicated team/budget to manage post-decree actions
- Use outside resources/consultants to assist/maintain compliance
- Develop protocols for future FDA inspections and communications

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Consent Decrees (cont'd)

- Do's
  - Internal investigation to vet FDA's observations / requirements
  - Prepare draft response/changes and allow time for DOJ review
  - Attempt to remove lower-level employees and hire counsel as needed for individuals
  - Establish joint defense for parties
  - Keep your FDA commitments and establish internal communication!
- Don'ts
  - Waste time fighting standard terms
  - Wait to notify affected parties
  - Assume the FDA provided you with all facts/information or understands impact for your customers or patients
  - Talk down to government lawyers!

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Criminal Prosecutions-FDA/OCI & DOJ

- Misdemeanors v. Felonies
  - Misdemeanor without showing of intent
  - Felony if done with intent to defraud or mislead or second offense without intent.
- Recommended for
  - Manufacturing/sale of counterfeit/unapproved products
  - Illicit Rx drug diversion, substitution, or tampering
  - Fraudulent health treatments or fraud with NDAs, PMAs, INDs/IDEs
  - Continuous, repeated, gross, flagrant, or intentional FD&C violation
  - Evidence of actual harm or public injury as result of FD&C violation.
- Penalties
  - Fines and civil money penalties, restitution, disgorgement, asset forfeiture
  - Strict liability for corporations/individuals.

Other Criminal Liability Provisions

- False Statements to Government Officials
- False Statements Relating to Health Care Matters
- Conspiracy to Mislead or Defraud the Government
- Mail and Wire Fraud
- Interstate Transportation of Stolen or Counterfeit Goods
- Obstruction of Agency Proceedings/Criminal Investigations
- Other statutes - health care-related violations – FDA-regulated products
  - Federal Anti-Tampering Act – FBI has concurrent jurisdiction
  - Anti-Kickback Act – knowingly seeking/paying for referral of service
  - Stark Law – physicians refer services to entities w/ financial interest
  - False Claims Act (qui tams) – whistleblower suits on behalf govt.
  - Controlled Substances Act – DEA enforces/sets and FDA recommends.

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Prevention Tactics:
Your Best Defense!

Prevention Tactics

- Maintain culture of regulatory compliance
- Do not shield or insulate executives
- Develop and maintain effective training for compliance
- Develop quality metrics and follow them throughout organization
- Run audits before/between inspections and take corrective action
- Fix FDA/state authority observations/483 violations and evaluate full quality system for developing better cGMP compliance
- Re-run audits after inspections and take corrective action

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International Harmonization

International Harmonization

- Regulatory Harmonization and Convergence – CBER
  - APEC (Asia-Pacific Economic Cooperation)
    - LSIF (Life Sciences Innovation Forum)
      - RHSC (Regulatory Harmonization Steering Committee)
        - » Topics: supply chain integrity, quality, pharmacovigilance, good review, multi-region clinical trials, good clinical practice inspection, cell and tissue-based products, biotherapeutics.

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International Harmonization (cont'd)

- ICH (Swiss Association, International on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use)
  - New members / observers and governance
    - Original countries - US, Europe, Japan – newer members Canada, Switzerland, Brazil, China, Korea
    - Original industry – EFPIA, JPMA, PhRMA – newer BIO, IGBA, WSMI
  - Focus to establish harmonized guidelines through scientific consensus process of regulatory and industry experts – finalized guidelines are published in the *Federal Register*.

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International Harmonization (cont'd)

- IMDRF - International Medical Device Regulators Forum
  - Primarily interfaces with CDRH but some device/biologics such as cell separators, blood collection, HIV screening
  - Australia, Brazil, Canada, China, Europe, Japan, Russia, US – observers WHO, APEC/LSIF, and other affiliates.
- IPRF - International Pharmaceutical Regulators Forum
  - Regulator-only discussions often at same time ICH
  - Sharing of ideas and regulatory cooperation
  - Working groups include (CDER/CBER members)
    - Gene therapies, cell therapies, good clinical practices, biosimilars, nanomedicines, and ID of medicinal product standards.

International Harmonization (cont'd)

- PANDRH - Pan American Network for Drug Regulatory Harmonization
  - PAHO – Pan American Health Organization and National Regulatory Authorities initiative
  - Focus on quality, safety, effectiveness and rational use of health products with NRAs
  - CBER participates with CDER, CDRH, ORA, OIP/OC.

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“Cluster” Meetings

- FDA and EMA holds regular meetings by phone or video with other regulators including for some Health Canada, Japan PMDA, Australian TGA
- Examples include
  - Advanced-therapy medicinal products (FDA/EMA/HC)
  - Biosimilars (FDA/EMA/HC/PMDA)
  - Blood products (FDA/EMA/HC)
  - Oncology (FDA/EMA/HC/PMDA/TGA)
  - Orphan medicinal products (FDA/EMA)
  - Pediatric medicinal products (FDA/EMA/HC/PMDA/TGA)
  - Patient engagement (FDA/EMA)
  - Pharmacogenetics (FDA/EMA/PMDA)
  - Pharmacometrics (FDA/EMA/HC/PMDA)
  - Pharmacovigilance (EMA/FDA)
  - Vaccines (FDA/EMA/HC)
  - Veterinary medicinal products (FDA/EMA)

Project Orbis

- Initiated in 2019 by FDA Oncology Center of Excellence for concurrent oncology product submission/review by international partners
- Partners include FDA, HC, TGA started and now includes Brazil, Israel, Switzerland, UK
- Criteria includes high impact, clinically-significant, priority review – BLAs and NDAs
- May still participate in other programs e.g., Real-Time Oncology Review, and each agency retains own timelines
- Regulatory agencies share their data analyses but retain own authority

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Imports

Importation from Foreign Sources

- Unapproved drugs/biologics may not be imported under FD&C Act including foreign-made versions of US-approved products
- Subject to inspection at time of entry by US Bureau of Customs & Border Protection (Customs, part of Division of Homeland Security)
- Potentially violative products may be
  - Detained until reconditioned, destroyed, or re-exported
  - Appearance unapproved/misbranded/adulterated sufficient
  - Controlled drugs subject to DEA enforcement.
- Foreign manufacturers must register to import (US agent required)
- Importer must provide entry notice and bond with Customs pending entry and provides the FDA opportunity to inspect
- FDA issues Import Alerts to help identify problem products

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Import for Export

- Certain unapproved/otherwise violative articles may be imported if for further processing or incorporation into products that will be exported from the U.S. by initial owner or consignee
- Must include statement that confirms intent for further processing and may be refused admission if credible evidence not intended for further processing

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Importation/Exportation for Emergency Use

- May be imported/exported under an Emergency Use Authorization (EUA) during effective period of declaration, contingent upon terms and conditions including, if exported, whether foreign country can comply with necessary and appropriate conditions of use
- EUA required - determination by Homeland Security/DoD there is a (potential) domestic or military emergency involving chemical, biological, radiological, or nuclear warfare hazard OR public health emergency or material thereat to affect national security or health and security of US citizens

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Exports

Exporting Unapproved Biologicals and Vaccines

- Export certificates typically requested by foreign governments to confirm regulatory/marketing status
- Unapproved products under FDA Export Reform and Enhancement Act of 1996
  - Must be labeled in accordance with requirements & conditions in foreign country and FD&C Act (e.g., if not approved in the US, must so state)
  - Notification not required if for investigational use
  - May be exported for tropical/rare US diseases
  - Partially-processed (requires purification, inactivation, fractionation, or significant chemical modification) biological products if not in form for prevention, treatment, or cure – and not intended for US sale and intended for further processing outside US, cGMP held.

Questions

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