FDA Survey of Commercial Drug Product Importers

Please enter your password to login:_____

This survey is being administered by FDA's contractor, Eastern Research Group, Inc. (ERG). Your responses and participation in this survey are PRIVATE. ERG will compile the aggregated results; no individual company's responses will be identified to FDA. This survey is unrelated to any enforcement activity.

The purpose of the survey is to provide FDA's Office of Planning with information that will help FDA to:

- Make importing safe, effective, high-quality drug products for human or animal use and their components more efficient.
- Enhance the protection of U.S. consumers from exposure to potentially unsafe imported drug products.
- Understand how commercial drug importers are dealing with safety and quality issues that may affect imported products.
- Understand how practices may differ due to the different characteristics of the product(s) being imported.

Terms highlighted in the text are defined in popup windows that can be viewed by placing the cursor over the term.

The survey software will save your responses as you move from page to page, so if you are interrupted, when you log in again you can start where you left off.

If you have any questions about the survey, please call the survey helpline at 1-800-xxx-xxxx or email us at FDAsurveyhelp@erg.com.

Survey Completion

0% 100%

QUESTIONS ABOUT THE SURVEY?
Call the Survey Helpline at 1-866-XXX-XXXX or email FDAsurveyhelp@erg.com.
NOTE: Responses are saved each time you click "Continue" or "Save and Continue." Therefore, you may stop this questionnaire at any time by closing your browser window. You can resume at the same point by logging in again with your password.
Helpful Links
Instructions and Acronyms

YOUR COMPANY

1. According to our records, your company imported drug products into the United States during the 2016 calendar year. Is this correct? **(Please note that "drug products" include such items as fluoride toothpaste, antiperspirants, dandruff shampoo, sun blocking lotions, antiseptics, as well as prescription and over-the-counter drugs intended for use on animals or humans.)**

   ❍ YES [GO TO Q3.]
   ❍ NO

2. [If NO to Q1.] Can you say how or why your company might have come to be named as the consignee or importer of record of a foreign-sourced pharmaceutical product in 2016? [Please describe.]_____
   _____

[Programmer Note: Skip to Q7..]

3. Please read the statements below regarding your imported drug products or components and check the appropriate response.

   3.a. All of our imported drug products or components are manufactured by our company – or our parent company – for export to the United States.

   ❍ YES [GO TO Q7.]
   ❍ NO

   3.b. All of our imported drug products are designated as investigational new drugs (INDs).

   ❍ YES [GO TO Q7.]
   ❍ NO

   3.c. All of our imported drug products are used in-house or are for personal use by employees.

   ❍ YES [GO TO Q7.]
   ❍ NO

   3.d. Our company only deals with the logistics—i.e., transportation and/or storage—of imported drug products.

   ❍ YES [GO TO Q7.]
   ❍ NO

4. Please indicate if your company imported any of the drug product types listed below in CY 2016. Note that some drug products may be included in more than one category. For example, insulin could qualify as an injectable drug and as a prescription drug, so if you imported insulin, you would check YES for both types.

[Programmer Note: The follow-up questions for each of the drug product types listed below should only appear if the respondent indicates importing the drug type.]

4.a. Active pharmaceutical ingredients (APIs)?

❍ YES
❍ NO
❍ DON'T KNOW

4.a.i [If YES to Q4.a] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.a.ii [If YES to Q4.a] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.b. Inactive pharmaceutical ingredients?

❍ YES
❍ NO
❍ DON'T KNOW

4.b.i [If YES to Q4.b] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.b.ii [If YES to Q4.b] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.c. Over-the-counter (OTC) drugs?

❍ YES
❍ NO
❍ DON'T KNOW

4.c.i [If YES to Q4.c] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.c.ii [If YES to Q4.c] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.d. Prescription drugs?

❍ YES
❍ NO
❍ DON'T KNOW

4.d.i [If YES to Q4.d] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.d.ii [If YES to Q4.d] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.e. Injectable drugs?

❍ YES
❍ NO
❍ DON'T KNOW

4.e.i [If YES to Q4.e] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.e.ii [If YES to Q4.e] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.f. Controlled substances?

❍ YES
❍ NO
❍ DON'T KNOW

4.f.i [If YES to Q4.f] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.f.ii [If YES to Q4.f] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.g. Drug products requiring New Drug Applications (NDAs) or New Animal Drug Applications (NADAs)?

❍ YES
❍ NO
❍ DON'T KNOW

4.g.i [If YES to Q4.g] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.g.ii [If YES to Q4.g] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.h. Drug products requiring Abbreviated New Drug Applications (ANDAs) or Abbreviated New Animal Drug Applications (ANADAs)?

❍ YES
❍ NO
❍ DON'T KNOW

4.h.i [If YES to Q4.h] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.h.ii [If YES to Q4.h] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.i. Drug products in compliance with an OTC monograph?

❍ YES
❍ NO
❍ DON'T KNOW

4.i.i [If YES to Q4.i] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.i.ii [If YES to Q4.i] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.j. Products that treat physical conditions and/or are intended to affect the structure or any function of the body (e.g., dandruff shampoo, fluoride toothpaste, skin moisturizer with sun block, etc.)?

❍ YES
❍ NO
❍ DON'T KNOW

4.j.i [If YES to Q4.j] Did you take ownership of the imported products?

❍ YES
❍ NO

❍ DON'T KNOW

4.j.ii [If YES to Q4.j] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

4.k. Other [please explain] _____

❍ YES
❍ NO
❍ DON'T KNOW

4.k.i [If YES to Q4.k] Did you take ownership of the imported products?

❍ YES
❍ NO
❍ DON'T KNOW

4.k.ii [If YES to Q4.k] Did you offer the imported products for sale to consumers or other organizations?

❍ YES
❍ NO
❍ DON'T KNOW

5. Which of the following statements describe your company's reason(s) for importing drug product(s) into the United States? **Please check all that apply.**

❒ Drug products comparable to those we import are not available in the United States market.
❒ Drug products comparable to our imports are more expensive in the United States market.
❒ We are importing drug products to meet U.S. demand that is not being met by domestic suppliers or other importers.
❒ Our customers prefer our imported drug products to other comparable products available to them.
❒ Other [please explain] _____
❒ Don't know

6. Is importing drug products and selling them in the United States to consumers or to other organizations your company's main line of business?

❍ YES [GO TO Q8.]
❍ NO

❍ DON'T KNOW

7. What is your company's main line of business? [Please describe.]_____
_____

8. How many employees does your company have?

❍ 20 employees or less
❍ 20 to 100 employees
❍ 100 to 150 employees
❍ 150 to 200 employees
❍ 200 to 250 employees
❍ 250 to 500 employees
❍ 500 to 750 employees
❍ 750 to 1,000 employees
❍ 1,000 to 1,250 employees
❍ 1,250 to 1,500 employees
❍ Greater than 1,500 employees

9. What was the total annual revenue of your company in FY 2016?

❍ $750,000 or less
❍ > $750,000 to $5.5 million
❍ > $5.5 million to $7.5 million
❍ > $7.5 million to $11.0 million
❍ > $11.0 million to $15.0 million
❍ > $15.0 million to $18.0 million
❍ > $18.0 million to $25.0 million
❍ > $25.0 million to $32.0 million
❍ > $32.0 million to $36.5 million
❍ > $36.5 million to $38.5 million
❍ Greater than $38.5 million

[Programmer Note: If Q1. = NO or Q3.a = YES or Q3.b = YES or Q3.c = YES or Q3.d = YES, then go to END. Otherwise CONTINUE.]

IMPORT DRUG PRODUCT SAFETY AND QUALITY

10. Sometimes, imported drug shipments may be mishandled during transport—for instance, exposed to extreme heat, cold, or humidity. Does your company have a method for assessing the risk of harm to consumers of your imported drug products if they are not handled correctly during transport by you or your suppliers?

❍ YES
❍ NO

❍ DON'T KNOW

11. [If YES to Q10.] Which of the following describes the criteria you use for assessing risk of harm to consumers of your imported drug products if they are not handled correctly by you or your suppliers? **Please check all that apply.**

❍ Type of drug product
❍ Number of points at which shipment is vulnerable to mishandling
❍ Severity of potential health effects caused by mishandling
❍ Size of eventual patient population
❍ Country of origin
❍ Other (please specify): _____

12. Does your company have a *written* plan that ensures that the quality is maintained for the drug products you are importing?

❍ YES
❍ NO [GO TO Q14.]
❍ DON'T KNOW [GO TO Q14.]

13. Does your imported drug product quality management plan cover any of the following elements?

13.a. Assigning personnel responsible for imported drug product quality and compliance.

❍ YES
❍ NO
❍ DON'T KNOW

13.b. Training for drug product quality and compliance personnel.

❍ YES
❍ NO
❍ DON'T KNOW

[Programmer Note: The follow-up questions listed below should only appear if the respondent indicates having a training program in Q13.b.]

13.b.i [If YES to 13.b] Does your training cover the following?

13.b.i.1 U.S. import requirements?

❍ YES
❍ NO
❍ DON'T KNOW

13.b.i.2 Host country export requirements?

❍ YES
❍ NO
❍ DON'T KNOW

13.b.i.3 Customs-Trade Partnership Against Terrorism (C-TPAT) requirements?

❍ YES
❍ NO
❍ DON'T KNOW

13.b.i.4 Customs and Border Protection (CBP) requirements?

❍ YES
❍ NO
❍ DON'T KNOW

13.b.i.5 Transportation Security Administration (TSA) cargo certification requirements?

❍ YES
❍ NO
❍ DON'T KNOW

13.b.i.6 Current good manufacturing practices (CGMPs)?

❍ YES
❍ NO
❍ DON'T KNOW

13.b.i.7 Other FDA requirements, such as registration and listing?

❍ YES
❍ NO
❍ DON'T KNOW

13.b.i.8 Ability to recognize risk to shipment integrity?

❍ YES
❍ NO
❍ DON'T KNOW

13.b.ii [If YES to 13.b] What is the frequency of your training program?

❍ Initial training upon hire only
❍ Initial training upon hire and sporadic refresher sessions
❍ Initial training upon hire and annual refresher sessions
❍ Initial training upon hire and bi-annual refresher sessions

❍ Other [Please explain.]_____

13.c. Recordkeeping for drug product quality and compliance activities.

❍ YES
❍ NO
❍ DON'T KNOW

13.d. When and how to assess the risks associated with your drug product importation.

❍ YES
❍ NO
❍ DON'T KNOW

13.e. System or protocol for sharing drug product quality and compliance information.

❍ YES
❍ NO
❍ DON'T KNOW

13.f. Quality assurance program or procedures for ensuring the quality of imported drugs.

❍ YES
❍ NO
❍ DON'T KNOW

13.g. Periodic audit of your entire imported drug quality and compliance plan.

❍ YES
❍ NO
❍ DON'T KNOW

14. Does your company apply more stringent procedures to assure the quality and compliance of drug products that have greater potential for harm?

❍ YES
❍ NO
❍ DON'T KNOW
❍ Check here if you import only one drug, or if your drug imports all have the same potential for harm

15. How does your company determine that your imported drug products comply with U.S. requirements? **Please check all that apply and add any further information in the space provided under "Other."**

❐ We check the FDA's Drug Establishments Current Registration Site web page to make sure each of our suppliers is currently registered with FDA.

❒ We receive documentation of FDA approval and/or compliance with FDA requirements from each of the companies whose drug products we import.
❒ We expect the foreign manufacturers and exporters that we have been dealing with to alert us to any regulatory issues regarding their products.
❒ Other [please explain]_____

16. Do you check and make sure that each drug product you import is on the list of products that the foreign manufacturer has submitted to FDA?

❍ YES
❍ NO
❍ DON'T KNOW

17. For each applicable drug, do you check that the foreign manufacturer has filed an NDA, NADA, ANDA, ANADA or that the drug conforms to an OTC monograph?

❍ YES
❍ NO
❍ DON'T KNOW

18. Does your company require the supplier(s) of your imported drug products to document that the drug products were manufactured in accordance with U.S. Current Good Manufacturing Practices (CGMPs)?

❍ YES
❍ YES, for some, but not all
❍ NO
❍ DON'T KNOW

19. Does your company have an established *written* procedure to verify that a drug product you are importing has not been adulterated or misbranded?

❍ YES
❍ NO
❍ DON'T KNOW

20. Does your company have an established *written* procedure to verify that the product labels of each of your import shipments contain all required information?

❍ YES
❍ NO
❍ DON'T KNOW

21. Does your company require or receive a certificate of analysis (COA) for any drug products that you import?

❍ YES

❍ YES, for some, but not all
❍ NO
❍ DON'T KNOW

22. Do you perform your own testing to confirm the results of a COA you receive from a supplier?

❍ YES
❍ NO
❍ DON'T KNOW

23. [If YES to Q22.] How frequently do you perform testing to confirm the results of a COA from a manufacturer/supplier? [Please describe]_____
_____

24. At the time of import entry, does your company have any documentation to indicate that the drug product and/or its manufacturer complies with country-of-export regulations?

❍ YES
❍ YES, for some shipments, but not all
❍ NO
❍ DON'T KNOW

25. [If YES to Q24.] Please describe that information or documentation.
_____
_____

26. At the time of import entry, could your company provide documentation that your imported drug product(s) comply with Current Good Manufacturing Practices (CGMPs) requirements?

❍ YES
❍ YES, for some shipments, but not all
❍ NO
❍ DON'T KNOW

27. [If YES to Q26.] Please describe that documentation. _____
_____

28. At the time of import entry, does your company have any documentation available to indicate that the drug product(s) were inspected by a foreign government or foreign governmental agency?

❍ YES
❍ YES, for some shipments, but not all
❍ NO

❍ DON'T KNOW

29. [If YES to Q28.] Please describe that documentation. _____
_____

30. Does your company know when the manufacturers of your imported drug products were last inspected by the FDA?

❍ YES
❍ YES, for some manufacturers, but not all
❍ NO
❍ NO, but we can easily find out
❍ DON'T KNOW

31. Does your company know when the manufacturers of your imported drug products were last inspected by a recognized foreign health authority?

❍ YES
❍ YES, for some manufacturers, but not all
❍ NO
❍ NO, but we can easily find out
❍ DON'T KNOW

32. Does your company perform periodic *written* evaluations of your suppliers' quality systems and supply chain?

❍ YES
❍ NO
❍ DON'T KNOW

33. [If YES to Q32.] How frequently do you perform these evaluations?

❍ On an as-needed basis
❍ Every 6 months
❍ Annually
❍ Every two years
❍ Every three years
❍ Every four years
❍ Every five years
❍ Other [Please explain.]_____

34. Does your company perform its own on-site audits of the manufacturers and/or suppliers of your imported drug products?

❍ YES
❍ YES, for some manufacturers and/or suppliers, but not all
❍ NO

❍ DON'T KNOW

35. [If YES to Q34.] How frequently do you perform these on-site audits?

❍ On an as-needed basis
❍ Every 6 months
❍ Annually
❍ Every two years
❍ Every three years
❍ Every four years
❍ Every five years
❍ Other [Please explain.]_____

36. Does your company employ or otherwise contract for the services of a regulatory specialist on drug product importation—such as an attorney or consultant—to ensure that your imported drug products and suppliers are in compliance with current FDA requirements?

❍ YES
❍ NO
❍ DON'T KNOW

37. Does your company have *written* agreements with your imported drug product manufacturers and/or suppliers, specifying your requirements and defining roles, responsibilities, and communication processes for all parties in the supply chain?

❍ YES
❍ YES, for some manufacturers and/or suppliers, but not all
❍ NO
❍ DON'T KNOW

INTEGRITY OF SHIPMENTS—QUALITY ASSURANCE

38. Does your company participate in a supply chain security program, such as the Customs-Trade Partnership Against Terrorism (C-TPAT) II or III, or TSA's cargo certification program?

❍ YES
❍ NO
❍ DON'T KNOW

39. Are the facilities that manufacture your imported drug products registered and inspected by FDA?

❍ YES
❍ YES, for some facilities, but not sure about all
❍ NO
❍ DON'T KNOW

40. Do the facilities that manufacture your imported drug products have certificates of approval from the foreign local government and/or foreign local inspection agencies?

❍ YES
❍ YES, for some facilities, but not sure about all
❍ NO
❍ DON'T KNOW

41. Are your drug product shipment brokers and all import transportation providers certified by the Customs-Trade Partnership Against Terrorism (C-TPAT)?

❍ YES
❍ YES, for some brokers or transporters, but not sure about all
❍ NO
❍ DON'T KNOW

42. Can the facilities that manufacture your imported drug products provide you with their quality control procedures and approvals for each product's lot production and storage and safety condition?

❍ YES
❍ NO
❍ DON'T KNOW

43. Do you have a method of assuring that arriving drug product shipments have been transported in conditions (e.g., temperature, humidity) required for that product?

❍ YES
❍ NO
❍ DON'T KNOW

44. [If YES to Q43.] What is that method? **Please check all that apply.**

❒ Inspection of shipment at point of entry by our company representative.
❒ Documentation of shipping conditions provided by shipper.
❒ Documentation of shipping conditions provided by manufacturer.
❒ Examination of shipment upon arrival at our distribution or retail location.
❒ Other [please explain] _____

45. Do you have a system in place to assure the security of your drug product shipments during transport from the point of export to the U.S.?

❍ YES
❍ NO
❍ DON'T KNOW/NOT SURE

46. [If YES to Q45.] Please briefly describe that system._____
_____

47. Do you have a system in place to assure the security of your drug product shipments during transport after the shipments arrive in the U.S.?

❍ YES
❍ NO
❍ DON'T KNOW/NOT SURE

48. [If YES to Q47.] Please briefly describe that system._____
_____

49. Did you have any of the following quality problems with **any** of your imported drug product shipments during CY 2016?

49.a. Product packaging was damaged.

❍ YES
❍ NO
❍ DON'T KNOW

49.b. Product was exposed to extremes of temperature or humidity that were beyond recommended ranges.

❍ YES
❍ NO
❍ DON'T KNOW

49.c. Product shipped was expired.

❍ YES
❍ NO
❍ DON'T KNOW

49.d. Product shipped was not the product we ordered.

❍ YES
❍ NO
❍ DON'T KNOW

49.e. Product on shipment package label was not product in package.

❍ YES
❍ NO
❍ DON'T KNOW

49.f. Product's label did not meet FDA specifications

❍ YES
❍ NO
❍ DON'T KNOW

49.g. Product was found to be of poor quality when examined or tested.

❍ YES
❍ NO
❍ DON'T KNOW

49.h. Other [please describe]_____

50. If you do have a problem with the quality of an imported shipment, what corrective action(s) do you take? **Please check all that apply.**

❒ Notify FDA.
❒ Notify supplier.
❒ Other [please describe] _____

REGISTRY OF COMMERCIAL DRUG PRODUCT IMPORTERS

51. If FDA created a registry of importers of commercial drug products, asking for a list of all imported drug products and their components, would your company voluntarily register? Your company would possibly be asked to provide the routes and ports used by your imported drug product shipments, as well as documentation of the licenses and approvals of the manufacturers or suppliers of your drug product imports.

❍ YES
❍ NO
❍ DON'T KNOW

52. [If NO or DON'T KNOW to Q51.] Why do you think your company would not (or might not) register if FDA established a Registry of Drug Product Importers? [Please explain.]_____
_____

53. If FDA instituted a certified importer program for "highly compliant" drug product importers which would allow members to have their incoming shipments expedited, do you think your company would apply? Such a program would require an FDA audit of your import product safety practices and your supply chain security practices; once approved, your import shipments would be expedited.

❍ YES
❍ NO

❍ DON'T KNOW

54. [If NO or DON'T KNOW to Q53.] Why do you think your company would not (or might not) choose to apply if FDA had a "certified importer" program? [Please explain.]_____
_____

55. What type of international commerce terms are *most often* used in your sales contracts for importing drug products into the United States? **Please check only one.**

❍ EXW (Ex Works)
❍ FCA (Free Carrier)
❍ CPT (Carriage Paid To)
❍ CIP (Carriage & Insurance Paid to)
❍ DAT (Delivered At Terminal)
❍ DAP (Delivered At Place)
❍ DDP (Delivered Duty Paid)
❍ FAS (Free Alongside Ship - named port of shipment)
❍ FOB (Free On Board - named port of shipment)
❍ CFR (Cost and Freight)
❍ CIF (Cost, Insurance and Freight)
❍ Other [please describe]_____
❍ Don't know

END.

Thank you for your participation.