

[Next Page](#)**UNITED STATES ACTIVE PHARMACEUTICAL INGREDIENT INDUSTRIAL BASE ASSESSMENT****SCOPE OF ASSESSMENT**

The U.S. Department of Commerce, Bureau of Industry and Security (BIS), Office of Strategic Industries and Economic Security (SIES), in partnership with the Department of Health and Human Services' Office of Industrial Base Management and Supply Chain (IBMSC), is conducting a survey of U.S. small-molecule active pharmaceutical ingredient (API) manufacturers, distributors and their suppliers of raw or starting materials; and finished dose form manufacturers and their suppliers. The survey results will be incorporated into a comprehensive report that presents the current state of the U.S. API industrial base, including existing supply chain vulnerabilities, production capacities, emergency response capabilities, and other trends from the survey data analyses. Additionally, the report will give recommendations to help improve the resiliency of the U.S. API supply chain in the face of future public health emergencies.

RESPONSE TO THIS SURVEY IS REQUIRED BY LAW

A response to this survey is required by law (50 U.S.C. § 4555). Failure to respond can result in a maximum fine of \$10,000, imprisonment of up to one year, or both. Information furnished herewith is deemed confidential and will not be published or disclosed except in accordance with Section 705 of the Defense Production Act of 1950, as amended (50 U.S.C. § 4555). Section 705 prohibits the publication or disclosure of this information unless the President determines that its withholding is contrary to the national defense. Information will not be shared with any non-government entity, other than in aggregate form. The information will be protected pursuant to the appropriate exemptions from disclosure under the Freedom of Information Act (FOIA), should it be the subject of a FOIA request.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number.

BURDEN ESTIMATE AND REQUEST FOR COMMENT

Public reporting burden for this collection of information is estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to BIS Information Collection Officer, Room 6883, Bureau of Industry and Security, U.S. Department of Commerce, Washington, D.C. 20230, and to the Office of Management and Budget, Paperwork Reduction Project (OMB Control No. 0694-0119), Washington, D.C. 20503.

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General Instructions	
A.	<p>Your organization is required to complete this survey on the U.S. Active Pharmaceutical Ingredient (API) industrial base.</p> <p>Your organization has been identified as a manufacturer, distributor, supplier, or service provider of a product or input required in the manufacturing of small-molecule APIs listed in section 3a. 'API Capabilities' of this survey.</p> <p>You must complete the survey using the Microsoft Excel-based template which can be downloaded from: https://www.bis.doc.gov/index.php/api-survey</p> <p>For your convenience, a PDF version of the survey and required drop-down content is available at https://www.bis.doc.gov/index.php/api-survey to aid internal data collection. DO NOT SUBMIT the PDF version of the survey as your response to BIS. Should this occur, your organization will be required to resubmit the survey in Excel format.</p>
B.	<p>Respond to every question. Surveys that are incomplete will be returned for completion. Use the comment boxes at the bottom of each section to provide any supplemental information. Make sure to record a complete answer in the cell provided, even if the cell does not appear to expand to fit all the information. Refer to the "Definitions" section while completing the survey.</p> <p>Fill out the survey section in sequential order and AVOID SKIPPING SECTIONS. Some information will auto-generate based on responses in previous sections.</p> <p>DO NOT COPY AND PASTE RESPONSES WITHIN THIS SURVEY. Inputs to the survey are to be made via keyboard or drop-down menus. The use of copy/paste can corrupt the file. If your submittal is corrupted due to copy/pasted responses your organization will be required to download an additional survey and resubmit.</p>
C.	<p>Do not disclose any <u>classified</u> information in this survey form.</p>
D.	<p>Submit your completed survey via email to APISurvey@bis.doc.gov</p> <p>For additional data protection, you may password-protect your survey prior to submission. Please send the password in a separate e-mail to APISurvey@bis.doc.gov.</p>
E.	<p>Questions related to the survey content should be directed to BIS survey support staff at APISurvey@bis.doc.gov</p> <p>Email is the preferred method of contact.</p>
F.	<p>For questions related to the overall scope of the industrial base survey and assessment, contact APISurvey@bis.doc.gov or:</p> <p>Erika Maynard Acting Director, Defense Industrial Base Division BIS/Export Administration/Office of Strategic Industries and Economic Security 1401 Constitution Avenue, NW, Room 3876 Washington, DC 20230</p> <p>DO NOT submit completed surveys to Ms. Maynard</p>
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Term		Definition	
Additive Manufacturing Process		Process that builds an object by sequentially building 2-dimensional (2D) layers and joining each to the layer below, allowing manufacturers to rapidly produce alternative designs without the need for retooling and to create complex devices built as a single piece.	
Active Pharmaceutical Ingredients (APIs)		Any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.	
Authorizing Official		An executive officer of the organization or business unit or another individual who has the authority to execute this survey on behalf of the organization.	
Batch Manufacturing		A method of manufacturing where the products are made as specified groups or amounts, within a time frame. A batch can go through a series of steps in a large manufacturing process to make the final desired product.	
Business Continuity Plan		A document that consists of the critical information an organization needs to prevent and recover from an unplanned interruption in business operations.	
Capital Expenditures (CapEx)		Investments made by an organization in buildings, equipment, property, and systems where the expense is depreciated. This does not include expenditures for consumable materials, other operating expenses, and salaries associated with normal business operations.	
Continuous Manufacturing		An advanced manufacturing technology that sends materials produced during each process step directly and continuously to the next step for further processing, whereby input materials are continuously fed into production and transformed, and processed output materials are continuously removed.	
Chemical Abstracts Service (CAS) Number		A unique numerical identifier assigned by the Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature. Find CAS registry numbers here: https://commonchemistry.cas.org/ .	
Customer		An entity to which an organization directly delivers the product or service that it produces. A customer may be another organization or another facility owned by the same parent organization. The customer may be the end user for the item but often can be the immediate link in the supply chain, adding additional value before transferring the item to yet another customer.	
Distributor		An independent selling agent who has a contract to sell the products of a manufacturer.	
Drug Product		An active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Federal Food, Drug, and Cosmetic Act for distribution in the United States.	
End to End Manufacturing		A production process that takes a design from concept to creation without the assistance of a third party.	
Excipient		Any inactive ingredients that are added intentionally to therapeutic or diagnostic products, but they are not intended to exert therapeutic effects at the intended dosage, although they may act to improve product delivery.	
Exports		Shipments to destinations outside the United States.	
External Entity		A company (for profit or non-profit), institution (academic, professional, or commercial), or government agency that is not within your organization.	
Facility		A building or the minimum complex of buildings or parts of buildings in which an organization operates to serve a particular function, producing revenue and incurring costs for the company. A facility may produce an item of tangible or intangible property or may perform a service. It may encompass a floor or group of floors within a building, a single building, or a group of buildings or structures. A facility could include a group of related facilities at which organization employees work, together constituting a profit-and-loss center for the company, and it may be identified by a unique Data Universal Numbering System (DUNS) number.	
Fermentation		The use of bacteria, yeast, or fungi to produce a specific active ingredient or intermediate, which is then extracted and purified to create the final pharmaceutical product.	
Final or Finished Dose Form (FDF)		A tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.	
Fine Chemical		Fine chemicals are complex, single, pure chemical substances typically produced by traditional organic synthesis in multipurpose plants according to exacting specifications. They are used as starting materials for specialty chemicals, mainly pharmaceuticals and agrochemicals.	
Full-Time Equivalent (FTE) Employees		Employees who work for 40 hours in a normal work week. Convert part-time employees into "full-time equivalents" by taking their work hours as a fraction of 40 hours.	
Good Distribution Practice (GDP)		Part of quality assurance that ensures the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur throughout the distribution process.	
Good Laboratory Practice (GLP)		A managerial quality control system covering the organizational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, reported and retained (or archived).	
Good Manufacturing Practice (GMP)		Also referred to as "current Good Manufacturing Practices" or "cGMP," a system of regulations enforced by the U.S. Food and Drug Administration, that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the GMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories.	
Headquarters		A facility that serves as an organization's hub of operations with all branches or divisions reporting to it.	
Intermediate		A material produced during steps of the synthesis of a drug substance that undergoes further molecular change before it becomes a drug substance.	
International Union of Pure and Applied Chemistry (IUPAC) Name		A systematic method of naming organic chemical compounds as recommended by the International Union of Pure and Applied Chemistry. More information here: https://iupac.org/what-we-do/commercial-abbreviations/	
Inventory		The goods or materials an organization holds for its own use or for the ultimate goal of sale.	
Key Starting Material (KSM)		A raw material, an intermediate, or an active pharmaceutical ingredient that is used in the production of an active pharmaceutical ingredient and that is incorporated as a significant structural fragment into the structure of the active pharmaceutical ingredient.	
Lead Time		The amount of time from the point that an entity (vendor, producer/manufacturer, warehouse, distributor, supplier, and retailer) processes an order, manufactures a product, or prepares an order to the point it gets delivered to the customer.	
Logistics Management Information System		A system of records and reports used to aggregate, analyze, validate and display data from all levels of the logistics system that can be used to make logistics decisions and manage the supply chain.	
Manufacturing		Includes all operations of receipt of materials, production, packaging, repackaging, labeling, relabeling, quality control, release, storage, and distribution of APIs.	
Non-U.S. Facility		A facility that is physically located outside of the United States.	
On Demand Manufacturing		A manufacturing system in which products are only manufactured when needed and in quantities required.	
Organization		A company, firm, laboratory, or other entity that owns or controls the facility capable of manufacturing or distributing influenza vaccine products.	
Partnership		Any type of service or collaboration agreement between two parties under which proprietary information can be shared in either tangible or non-tangible forms.	
Production		The process of transforming inputs (raw materials, semi-finished goods, subassemblies, fill finish) into goods or services.	
Point of Care Manufacturing		The production of therapies in hospitals, carried out when there is no time for storing the medicine, which is delivered to the patient with no delays.	
Research and Development		Basic and applied research in the engineering sciences, as well as design and development of prototype products and processes. Efforts that an organization conducts towards innovating, introducing and/or improving products and processes.	
Sales		All reported and unreported sales of subject products, including sales to end-users, producers, financial entities, intermediaries, traders, distributors, et al.	
Single Use Technology		A manufacturing process designed for use for the duration of the production process of a single batch of therapeutics and then discarded.	
Small Molecule Active Pharmaceutical Ingredient (API)		A small molecule API is a low molecular weight organic compound that may regulate a biological process, bind specific biological macromolecules, and act as an effector, usually derived through chemical synthesis.	
Sole Source		A supplier that is the only source for the supply of parts, components, or services. No alternative U.S. or non-U.S. based suppliers exist other than the current supplier.	
Solution		A liquid preparations containing one or more drug substances molecularly dispersed in a suitable solvent or a mixture of mutually miscible solvents.	
Supplier		An entity from which your organization obtains inputs, which may be goods or services. A supplier may be another organization with which you have a contractual relationship, or it may be another facility owned by the same parent organization.	
Supply Chain Disruption		Any event causing a disruption or delay in production, sales, or distribution of products.	
Supply Chain Risk Management (SCRM) Program		A coordinated effort within an organization to help identify, monitor, detect and mitigate threats to the supply chain.	
Specialty Chemical		Single-chemical entities or formulations whose composition influences the performance and processing of the end product.	
Synthetic Biology Manufacturing		The creation of new genomes, biological pathways, or organisms not found in nature or the redesign of existing genomes, biological pathways, or organisms.	
United States		The "United States" or "U.S." includes the 50 states, the District of Columbia, Puerto Rico, Guam, America Samoa, the U.S. Virgin Islands, and the Northern Mariana Islands.	
U.S. Active Pharmaceutical Ingredients Industry		Industry comprised of organizations that engage in researching, developing, manufacturing, and/or distributing Active Pharmaceutical Ingredients incorporated into finished drug products available within the United States.	

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1. Organization Information

A.

Provide your organization's primary point of contact for this survey. This individual will be responsible for ensuring the completion and certification of this organization's survey.

Name	Title	Phone Number	Email Address	State

B.

Provide the following information for your organization.

1. Organization Name		Definition: Organization
2. Street Address		
3. City		
4. State		
5. ZIP Code (5-digit)		
6. Country		
7. Ultimate Parent Organization Name		
8. Ultimate Parent Organization Country		
9. Is your ultimate parent organization a public or private entity?		

If Public, Stock Ticker:

C.

Identify the sector(s) of the small-molecule active pharmaceutical ingredient (API) value chain that your organization supports for the U.S. and non-U.S. markets, then provide the percent of your organization's 2023 revenue attributed to each segment.

Sector of Small-Molecule API Value Chain	Market Participation	% of 2023 Revenue
1. Active Pharmaceutical Ingredient Manufacturer		
2. Starting Materials/Chemical Manufacturer		
3. Finished Dose Form Manufacturer		
4. Active Pharmaceutical Ingredient Distributor		
5. Starting Materials/ Chemical Distributor		
6. Finished Dose Form Distributor		
7. Research & Development		
8. Fill Finish Service Provider		
9. Other (specify in the box to the right)	Write in Here	

U.S. Market
Non-U.S. Market
Both U.S. and non-U.S. Market

D.

Describe the your organization's activities related to the pharmaceutical industry.

1.

Describe your organization's activities related to small-molecule active pharmaceutical ingredients (API) that occur within the United States.

2.

Company
Government
Individual

Access to Financial Resources
Access to Government Contracts
Access to Intellectual Property
Access to Suppliers or Reduced Lead Times
Broaden Customer Base
Creation of New Technologies/
Product Improvements
Develop New Capabilities
Improved Access to Foreign Markets (Required)
Improved Access to Foreign Markets (Voluntary)
Improved Access to U.S. Markets
R&D Access/Coordination
Reduce Costs
Risk Sharing
Shared/Improved Technology or Skills
Tax-related
Other (Specify here)

E.

List all entities in descending order, including individuals and governments, which currently hold 5% or more of your ultimate parent organization's voting rights.

Entity or Individual Name	Stake %	Entity Type	City	State	Country
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

F.

Record the total number of joint ventures that your organization has initiated since 2019 (include both U.S. and non-U.S. activities) in the box on the right, then identify the 5 joint ventures that are most critical to your organization's API manufacturing and/or distribution activities.

Joint Venture Name	Country	Partner Name	Primary Purpose	Year Initiated	Explain
1.					
2.					
3.					
4.					
5.					

Comments:

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2. Facilities

Provide your organization's total number of facilities that are involved in the manufacture and/or the distribution of the small-molecule API products listed in Section 3a and/or any inputs for the small-molecule products: (4) the current status of operations; (5) year of facility closure or opening if applicable; (6) the primary active pharmaceutical ingredient (API)-related business operations performed at the facility; (10) whether this facility is certified in accordance with current good manufacturing practices (cGMP); (11) year of most recent FDA inspection; (12) and type of the most recent FDA inspection.

[To view the small-molecule API products listed in Section 3a click here](#)

Definition: Facility
Definition: Finished Dose Form (FDF)
Definition: Key Starting Materials (KSM)

Facility Name	Location			Operating Status	Year of Facility Closure or Expected Opening	Operations		Manufacturing Model	2023 Capacity Utilization (%)	cGMP Certified?	Quality Assurance	
	(1) City	(2) State (if U.S.)	(3) Country			(6) Primary Operation	(7) Additional Operation				(11) Year of Recent FDA Inspection	(12) Type of FDA Inspection
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												
20.												
21.												
22.												
23.												
24.												
25.												
26.												
27.												
28.												
29.												
30.												

Answer the following questions regarding your organization's facility expansion plans and/or decisions to close API-related facilities as reported in Part A.

B.

1. Briefly describe your organization's facility expansion plans, as applicable.

2. Briefly describe your organization's decision to close API-related facilities, as applicable.

Comments:

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Operating
Idle/Standby
Planned/Expected
Recently Closed

API Distribution
API Manufacturing/Production
Fill Finish Services
FDF Distribution
FDF Manufacturing
Starting Materials Distribution
Starting Materials Manufacturing
Research & Development

Batch Manufacturing
Continuous Manufacturing
Both Batch and Continuous
Other (Specify Here)

Yes
No
Certification Pending
N/A

For-cause inspection
Pre-approval inspection
Surveillance inspection

OMB Control No. 0694-

API

FDF

Both API and FDF

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3a. Active Pharmaceutical Ingredients Product Capabilities

Identify the active pharmaceutical ingredient(s) (API) or finished dose form(s) (FDF) contained in the list of API(s) that your organization manufactured, distributed/sold in the U.S., had an idle capability to manufacture, or was in development in 2023 and provide the following information: (1) the capabilities of your U.S. operations; (2) the type of product; (3) your organization's assessment of the availability and location of alternative providers of that that provide the same product or an essentially equivalent product; (4) the primary country where your product is manufactured; and (5) the facility where the product was housed immediately prior to shipping to the customer

Active Pharmaceutical Ingredients (including Salt Form)	(1) Capability	(2) Product Type	(3) Assessment of Alternative Providers	(4) Primary Manufacturing Country	(5) Primary Facility
Acetaminophen					
Acyclovir					
Adenosine					
Albuterol					
Alteplase					
Amiodarone					
Ampicillin					
Apixaban					
Argatroban					
Aspirin					
Atropine					
Avibactam					
Azithromycin					
Bictegravir					
Bictegravir-Emtricitabine-Tenofovir Alafenamide					
Calcium					
Cefepime					
Ceftazidime-Avibactam					
Ceftazidime					
Ceftriaxone					
Chlorhexidine					
Dantrolene					
Daptomycin					
Dexamethasone					
Diphenhydramine					
Dobutamine					
Doxycycline					
Emtricitabine					
Epinephrine					
Etomidate					
Fentanyl					
Furosemide					
Haloperidol					
Hydralazine					
Hydromorphone					
Ibuprofen					
Ipratropium Bromide					
Isoflurane					
Labetalol					
Lactulose					
Levetiracetam					
Levofloxacin					
Levothyroxine					
Lidocaine					
Lidocaine-Epinephrine					
Linezolid					
Lorazepam					
Magnesium Sulfate					
Meropenem					
Methylprednisolone					
Metoprolol					
Metronidazole					
Micafungin					
Morphine					
Naloxone					
Nitroglycerin					
Norepinephrine					
Ondansetron					
Pantoprazole					
Penicillin G					
Phenylephrine					
Phenytoin					
Piperacillin					
Piperacillin-Tazobactam					
Potassium Chloride					
Propofol					
Rocuronium					
Sodium Bicarbonate (5% injection)					
Sodium Phosphate					
Succinylcholine					
Sulfamethoxazole					
Tacrolimus					
Tazobactam					
Tenofovir Alafenamide					
Thiamine					
Ticagrelor					
Trimethoprim					
Trimethoprim-Sulfamethoxazole					
Valganciclovir					
Vancomycin					
Vasopressin					
Vitamin K					
Voriconazole					
Comments:					

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Manufacture
Distribute
Idle-Capability
In Development

Sole Global Source
Existing Non-U.S. Competitors only
Existing U.S. Competitors only
Existing U.S. and Non-U.S. Competitors

List Generated from
Section 2

Comments:	
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3c. API Inputs

If your organization does not manufacture APIs, proceed to Section 4.

For each manufactured API product listed in the first column, provide that product's five most critical inputs. List the inputs in descending order, starting with the most critical. For each input, provide the following: input name, input type, the Chemical Abstracts Service (CAS) number, and the International Union of Pure and Applied Chemistry (IUPAC) name if known.

[Definition: International Union of Pure and Applied Chemistry \(IUPAC\) Name](#)
[Definition: Chemical Abstracts Service \(CAS\) Number](#)

Products (auto-generated from Section 3a)	Input #	Input Name	Input Type	CAS Number	IUPAC Name (if known)
	1.				
	2.				
	3.				
	4.				
	5.				
	1.				
	2.				
	3.				
	4.				
	5.				
	1.				
	2.				
	3.				
	4.				
	5.				
	1.				
	2.				
	3.				
	4.				
	5.				
	1.				
	2.				
	3.				
	4.				
	5.				
Comments:					

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Excipient
Fine Chemical
Purchased
Intermediate
Solution
Specialty Chemical
Other (Specify here)

Survey will allow for up to 50 possible products

4. Key Starting Materials Product Capabilities

Indicate whether your organization manufactures key starting materials (KSM) in the box on the right. If no, proceed to Section 5.

Identify the KSMs that your organization your organization manufactured, distributed/sold in the U.S., had an idle capability to manufacture, or was in development in 2023 and provide the following information: (1) the capabilities of your U.S. operations; (2) your organization's assessment of the availability and location of alternative providers of that that provide the same product or an essentially equivalent product; (3) the primary country where the product was manufactured; (4) the facility where the product was housed immediately prior to shipping to the customer; (5) the primary country of sourced inputs; (6) the share of input costs sourced from primary country; **ONLY COMPLETE COLUMNS 7-11 FOR PRODUCTS THAT YOUR ORGANIZATION MANUFACTURES**; (7) your organization's 2023 total output in kilograms (kg) or Liters (L); (8) the percentage of your 2023 output sold in the U.S.; (9) your organization's 2027 projected output in kg or L; (10) the estimated percentage of your organization's 2027 projected output to be sold in the U.S.; and (11) your organization's primary facility that manufactures the product.

Click here to write in Other Key Starting Materials

Key Starting Materials		(1)	(2)	(3)	(4)	Input Information		COMPLETE FOR MANUFACTURED PRODUCTS ONLY					
CAS Number	Chemical Name	Capability	Assessment of Alternative Providers	Primary Manufacturing Country	Primary Facility	Primary Country of Sourced Inputs	Share of Input Costs Sourced from Primary Country	2023 Total Output (kg or L)	Percent of 2023 Output Sold in the U.S.	2027 Projected Output (kg or L)	Estimated Percent of 2027 Output To Be Sold in the U.S.	Primary Manufacturing Facility	
50-81-7	Ascorbic Acid												
53-06-5	Cortisone												
56-40-6	Glycine												
56-81-5	Glycerol												
57-13-6	Urea												
58-27-5	Menadione												
59-88-1	Phenylhydrazine HCl												
60-12-8	2-Phenylethanol												
60-18-4	Tyrosine												
60-34-4	Methylhydrazine												
60-70-8	Veratramine												
62-53-3	Aniline												
63-42-3	Lactose												
63-68-3	L-Methionine												
64-18-6	Formic Acid												
64-19-7	Acetic Acid												
65-45-2	Salicylamide												
67-56-1	Methanol												
69-72-7	Salicylic Acid												
70-78-0	3-Iodo-L-tyrosine												
73-24-5	Adenine												
73-40-5	Guanine												
74-89-5	Methylamine												
75-05-8	Acetonitrile												
75-07-0	Acetaldehyde												
75-16-1	Methylmagnesium Bromide												
75-19-4	Chiral Cyclopropane												
75-31-0	Isopropylamine												
75-36-5	Acetyl Chloride												
75-50-3	Trimethylamine												
75-64-9	Tert-Butylamine												
75-75-2	Methanesulfonic Acid												
75-89-8	2,2,2-Trifluoroethanol												
76-41-5	Oxymorphone												
76-42-6	Oxycodone												
77-78-1	Dimethyl Sulfate												
78-95-5	Chloroacetone												
79-03-8	Propionyl Chloride												
79-04-9	Chloroacetyl Chloride												
87-62-7	2,6-Dimethylaniline												
88-69-7	2-Isopropylphenol												
90-02-8	Salicylaldehyde												
91-01-0	Diphenylmethanol												
91-57-6	2-Methylnaphthalene												
95-02-3	4-Amino-5-Aminomethyl-2-Methylpyrimidine												
95-73-8	2,4-Dichlorotoluene												
95-92-1	Acetaminophen												
97-93-8	Triethylaluminium												
98-95-3	Nitrobenzene												
99-40-1	2-Chloro-3',4'-Dihydroxyacetophenone												
99-93-4	4'-Hydroxyacetophenone												
100-00-5	1-Chloro-4-Nitrobenzene												
100-01-6	4-Nitroaniline												
100-06-1	4'-Methoxyacetophenone												
100-07-2	4-Methoxybenzoyl Chloride												
100-09-4	P-Anisic Acid												
100-46-9	Benzylamine												
101-41-7	Methyl Phenylacetate												
103-67-3	N-Methylbenzylamine												
103-63-9	Phenethyl Bromide												
Write-In Here	Other Starting Material 1	Write-In Here											
Comments:													

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Survey will allow for up to 25 write-in chemicals

Survey will include 258 discreet chemicals

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6. Customers

This section must be completed in its entirety, blank or "Not Applicable" responses will not be accepted. If you have less than 10 direct customers, specify in the comments section.

1. Identify your organization's top 10 customers by 2023 sales for the products listed in sections 3a and 4 of the survey and provide the postal code and country for each customer.

2. Identify the primary product that your organization sells to each customer, the end-use of that product, the brand or trade name of the finished dose form (FDF) if known, and the percentage of 2023 annual sales of the primary product attributed to each customer.

1. Customer Information			2. Product Information				
Customer Name	Customer Postal Code	Customer Country	Primary Product Sent to Customer	Product Type Sent to Customer	End Use of Primary Product	Brand Name of Finished Dose Form (if known)	Percent of 2023 Product Sales Attributed to Customer
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							

Identify your organization's top U.S. government and top non-U.S. government customers in 2023 if applicable.

1. Customer Information			2. Product Information				
Customer Country	Government Department/Office	Primary Product Sent to Customer	Product Type Sent to Customer	End Use of Primary Product	Brand Name of Finished Dose Form (if known)	Percent of 2023 Product Sales Attributed to Customer	
U.S.	United States						
Non-U.S.							

Comments:

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List Generated from
Sections 3A and 4

API
FDF
Both API and FDF

Pharmaceutical Use
Non-Pharmaceutical Use
Unknown
Other (Specify here)

Products in Section 3a and 4

Facilities list in Section 2

Resolved
Ongoing

Bought new equipment
Changed health and safety practice
Found new supplier
Found new transportation method
Hired additional employees
Hired cybersecurity firm
Implemented allocation plan
Increased human capital benefits
Relocated operations
Repaired equipment
Slowed production
Updated cybersecurity practices
Updated GMP practice
Updated waste disposal plan
Used product substitute
Other (specify here)

Consignment
Continuous Review
Drop Shipping
EOQ Without Safety Stock
Fixed Order Quantity
Fixed Period Ordering
Just-In-Time
Single-Period
Vendor-Managed Inventory
Other (specify here)

Fixed Level
Statistical (e.g., Z-score)
Time-based
Other (specify here)

Cost
Disruptions
Export regulations
Quality management
Visibility
Other (Specify here)

Availability
Lowest Price
Past Performance
Proximity to Manufacturing Location
Quality
Regulatory Compliance
Speed of Performance
Technical Capabilities
Other (Specify here)

Customs Issue
Cybersecurity Incident
Disease/Quarantine
Equipment Outage
Geopolitical Instability
GMP Quality Issue
Input Quality
Internal Labor Disruption
Natural Disaster
Regulatory/Environmental restrictions
Supplier Ended Production
Supplier Labor Disruption
Supplier Production Delays
Supplier Went Out of Business
Trade Dispute/Tariffs
Transportation Issue
Other (specify here)

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7. Supply Chain Practices

Describe your organization's most significant supply chain disruptions experienced between 2023-2024. List the disruptions in descending order beginning with the most significant and provide the following information for each disruption: (1) the product impacted; (2) the primary facility impacted; (3) the length of the disruption (in weeks); (4) the percent of product output impacted by the disruption; (5) the cause of the disruption; (6) the primary action taken to mitigate the disruption; (7) the status of the disruption; and (8) an explanation of the disruption.

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Product Impacted	Primary Facility Impacted	Length of Disruption (weeks)	Percent of Product Output Disrupted	Cause of Disruption	Primary Action Taken to Mitigate Disruption	Status of Disruption	Explain
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							

Answer the following questions regarding your organization's business continuity plan and supply chain management practices.

1. How often is your business continuity plan updated? If you do not have a plan, select "No Plan".

2. Describe the challenges that impede your organization's ability to shift production from one facility to another in the event of an unexpected shutdown.

3. How many square feet of your cGMP space is currently idle?

What percent of your idle cGMP space could be used to manufacture APIs within 12 months?

4. Identify the three most important factors your organization considers when selecting a supplier.

Top Factor	Second Factor	Third Factor	Explain

5. Identify the greatest challenge that your organization faces with respect to its inbound and outbound supply chain logistics and provide a brief explanation.

Challenge	Explain
Inbound Logistics	
Outbound Logistics	

6. Does your organization maintain a Supply Chain Risk Management (SCRM) program?

Briefly explain your SCRM program:

If yes, do you have an allocation plan?

Respond to the following questions regarding your organization's inventory management practices.

1. Identify your organization's primary inventory management strategy.

Provide a brief explanation

2. Indicate whether your organization maintains safety stock.

If so, what is your safety stock calculation method?

Comments

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8. Quality Control

Answer the following questions related to quality and hazardous chemicals.

A.

1. Is your organization Good Laboratory Practices (GLP) certified? [Definition: Good Laboratory Practice](#)

2. Is your organization Good Distribution Practices (GDP) certified or rely on a GDP-certified distributor? [Definition: Good Distribution Practice](#)

3. Do you utilize Laboratory Information Management System software? If yes, identify your organization's software provider.

4. Select the primary cost category associated with complying with regulations concerning the use, storage, and waste of hazardous chemicals and materials.

Explain

Identify your organization's products that have been impacted from quality-related issues between 2023-2024. Then provide the following information: (1) The product impacted from quality-related issues; (2) the type of quality issue experienced by product; (3) The related product input (if applicable); (4) your organization's immediate response to the issue; (5) the length of the impact; (6) the percent of product output disrupted by the quality issue; (7) the long term resolution to the quality issue; and (8) any additional explanation describing the issue and resolution.

	(1) Product	(2) Issue Type	(3) Related Input (if applicable)	(4) Immediate Response	(5) Length of Impact	(6) Percent of Product Output Disrupted	(7) Long Term Mitigation/ Resolution	(8) Additional Explanation
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
	Comments							

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Administrative and Legal
Containment Devices
Decontamination Systems
Safety Equipment and
Utilities
Training
Ventilation and Filtration
Systems
Waste Removal
Other (specify here)

Products from Section
3a and 4

Inputs from Section 3c

Biological impurities
Labeling issue
Low quality input
Metal impurities
Sanitation/Cleaning
Tracking issue
Other (specify here)

Employee Training
FDA Report
Stop production
Update GMP
Other (specify here)

Less than 1 month
1-5 months
6-12 months
1-2 years
2+ years
Ongoing

Changed cleaning
practices
Changed manufacturing
practices
Developed new test
Found new supplier
Used substitute
Other (specify here)
None

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9. Research and Technology

Provide (1) your organization's five most important external research and development partners for the products you identified in sections 3a and 4 of the survey. Then provide (2) the partner type; (3) the country that partner is located in; (4) the primary product application; (5) a short description of the R&D focus of that partnership.

(1) Partner Name	(2) Partner Type	(3) Partner Country	(4) Primary Product Application	(5) Description of R&D Activity
1.				
2.				
3.				
4.				
5.				

A.

Please indicate whether your organization currently utilizes or plans to invest in novel or innovative technologies in your manufacturing process (e.g. additive manufacturing, on-demand manufacturing, etc.) If yes, complete the table below.

Provide (1) your organization's product, (2) manufacturing technology type, (3) a brief description of the technology, (4) the year initial implementation or planned initial implementation, (5) the estimated year of scaled implementation, (6) the primary implementation challenge and (7) additional explanation of the technology and/or implementation challenge. If you are investing in a similar technology for more than one product, list all products.

(1) Product	(2) Manufacturing Technology	(3) Description of Technology	(4) Year of Initial Implementation	(5) Year of Scaled Implementation	(6) Primary Implementation Challenge	(7) Explain
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						

B.

Comments:

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Contract research organization
Non-profit research institute
Other private company
Other public company
University

Additive Manufacturing
Bio-manufacturing
End-to-End Manufacturing
Fermentation
On-Demand Manufacturing
Point of Care Manufacturing
Other (specify here)

Inadequate IT infrastructure
Incompatible equipment
Lack of qualified talent
Lack of R&D investment
Licensing and permits
Product development costs
Product purchase costs
Regulatory approval process
Unfamiliarity with technology
Other (specify here)

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10. Employment

Record the total number of full-time equivalent (FTE) employees for your U.S. operations for each year since 2021, including employees who work off-site, then provide the total number of current vacancies.

[Definition: Full Time Equivalent](#)

		2021	2022	2023	2024	2030 (estimate)	Total Number of Current Vacancies
A.	FTE Employees						

For each occupation type, identify (1) the total number of FTEs for each occupation type currently employed; (2) the number of current vacancies; (3) the estimated number of FTEs for each occupation type for the year 2030, (4) the type of workforce challenge most impacting that occupation; (5) the degree of challenge; and (6) a brief explanation.

	Occupation	(1) Current Number of FTEs	(2) Current Number of Vacancies	(3) Estimated Number of FTEs in 2030	(4) Top Workforce Challenge	(5) Degree of Challenge	(6) Explanation of Challenges
B.	1. Chemical/Biological Technicians						
	2. Biological Technicians						
	3. Packaging and Filling Machine Operators, and other Production Workers						
	4. Manufacturing/Process Engineers						
	5. Stockers, Order Fillers and Other Warehouse Workers						
	6. Chemists/Material Scientists						
	7. Biological Scientists/Biochemists						
	8. Regulatory Affairs						
	9. Inspectors, Testers, Sorters, Samplers, Weighers						
	10. Other Quality Control/Quality Assurance Workers						

Respond to the following questions related to your organization's use of automation.

	Response	Explanation
C.	1. Since 2020, has your organization reduced its workforce due to increased reliance of automated processes?	
	2. If Yes, please estimate the percentage of your workforce reduction.	
	3. Which occupation has been impacted the most by your organization's use of automation?	

Comments:

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Attracting workers to location
Employee turnover/retention
Finding experienced/qualified workers
Significant portion of workforce retiring
Training barriers
Visa Difficulty/Availability
None
Other (Specify here)

Yes
No

Minor
Moderate
Great
Severe
None

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11. Capital Equipment

In the box on the right, indicate whether your organization experienced capital equipment-related challenges that impeded its ability to meet customer demand between 2023-2024. If no, proceed to the next section.

Identify up to ten instances between 2023-2024 when capital equipment-related challenges impeded your organization's ability to meet customer demand and provide (1) the primary challenge; (2) the name of the equipment causing the challenge; (3) the equipment type; (4) the primary product associated with the challenge; (5) the primary manufacturer of the equipment; (6) that manufacturer's country; (7) the time to replace that equipment; (8) the number of training hours required to operate the equipment; (9) your organization's assessment of the availability and location of alternative providers of that that provide the same product or an essentially equivalent product; and (10) any additional comments.

(1) Primary Challenge	(2) Equipment Name	(3) Equipment Type	(4) Primary Product Associated	(5) Primary Equipment Manufacturer	(6) Primary Equipment Manufacturer Country	(7) Time to Replace	(8) Training Hours Required to Operate	(9) Assessment of Alternate Suppliers	(10) Comments
1.									
2.			Glycine						
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									
Comments									

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Cost to Replace
Impending
Obsolescence
Import/Export Controls
Prohibiting Purchase
Inability to Scale
Lack of Swing Space
Lack of Qualified
Operators
Maintenance Costs
No Longer Commercially
Available
No Longer Supported by
Manufacturer
Regulatory Compliance
Issue
Software Issues
Time to Replace
Other (Specify here)

Bioreactor/Fermenter
Centrifuge
Chiller
Clean Room Equipment
Conveyor
Crystallizer
Distiller
Dryer
Evaporator
Fill-Finish Equipment
Freezer
Heat Exchanger
HEPA Fan and/or Filter
Hopper
Humidity Control System
Inspection Equipment
Isolator (box with gloves)
Membrane Filter
Miller
Mixer/Blender
Overhead Condenser
Pressure Control System
Quality Testing Equipment
Reactor (non-bio)
Sterilization Equipment
Storage and Packaging
Temperature Monitoring and/or
Control System
Utilities and Support Equipment
Vacuum Pump
Other (Specify here)

Less than 1 month
1-5 months
6-12 months
1-2 years
3-4 years
5 years or more

Sole Global Source
Existing Non-U.S. Competitors only
Existing U.S. Competitors only
Existing U.S. and Non-U.S.
Competitors

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12. Government Support

Identify up to five U.S. federal, state, and/or local government programs that have provided the greatest benefit to your operations related to producing or distributing products identified in section 3a and 4 between 2019-2024. Then describe the objective or outcome of each program of support. These programs can be direct grants, tax incentives, export credits, utility provisions, or similar programs that provide direct benefits to your business operations.

Supporting U.S. Government Entity		Support Type	Year of First Benefit	Length of Support (years)	Support Value (U.S. Dollars)	Description of Support
1.						
2.						
3.						
4.						
5.						

Identify up to five non-U.S. government programs that have provided the greatest benefit to your operations related to producing or distributing products identified in section 3a and 4 between 2019-2024. Then describe the objective or outcome of each program of support. These programs can be direct grants, tax incentives, export credits, utility provisions, or similar programs that provide direct benefits to your business operations.

Supporting Non-U.S. Entity		Country	Support Type	Year of First Benefit	Length of Support (years)	Support Value (U.S. Dollars)	Description of Support
1.							
2.							
3.							
4.							
5.							

Comments:

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Biomedical Advanced Research and Development Authority (BARDA)
Centers for Disease Control and Prevention (CDC)
Defense Advanced Research Projects Agency (DARPA)
Defense Health Agency
Defense Logistics Agency (DLA)
Defense Security Cooperation Agency (DSCA)
Defense Threat Reduction Agency (DTRA)
Department of Veterans Affairs
Federal Emergency Management Agency (FEMA)
Food and Drug Administration (FDA)
Municipal Government
National Institutes of Health (NIH)
National Laboratories (DOE Labs)
Office of the Assistant Secretary for Preparedness and Response (ASPR)
State Government
U.S. Air Force
U.S. Army
U.S. Coast Guard
U.S. Intelligence Community
U.S. Marine Corps
U.S. Navy
Other Agency (Specify here)

Direct Monetary Grant
Export Credit Program
Export Lending
Import Duty Reduction
Land Grant or Lease
Loan Forgiveness or Guarantee
Provision of Infrastructure
Provision of Utilities
Tax Incentives
Worker Support or Training Programs
Other Program (Specify here)

Calendar Year
Fiscal Year

Previous Page		13. Financials						Next Page
<p>A. Indicate the reporting schedule and then record the financial line items in parts B through D for 2020-2024. All responses in this section must be reported in accordance with the selected schedule.</p>								
1. Reporting Schedule:								
		Record in \$ in the Thousands, e.g. \$12,000 = survey input of \$12						
		2020	2021	2022	2023	2024 (Estimate)		
Income Statement								
B.	1. Total Net Sales (and other revenue)							
	1.1 % Total API & KSM Sales (as a % of line 1)							
	1.2 % U.S. API & KSM Sales (as a % of line 1)							
	2. Cost of Sales / Cost of Goods Sold							
	3. Total Operating Income							
4. Earnings Before Interest and Taxes (EBIT)								
5. Net Income								
		Record in \$ in the Thousands, e.g. \$12,000 = survey input of \$12						
Balance Sheet		2020	2021	2022	2023	2024 (Estimate)		
C.	1. Cash and Cash Equivalents							
	2. Inventories							
	3. Current Assets							
	4. Total Assets							
	5. Current Liabilities							
	6. Total Liabilities							
	7. Retained Earnings							
	8. Total Owner's Equity							
		Record in \$ in the Thousands, e.g. \$12,000 = survey input of \$12						
Other		2020	2021	2022	2023	2024 (Estimate)		
D.	1. Research & Development (R&D) Expenditure							
	1.1 Internally-funded R&D Percentage (as a % of 1.)							
	1.2 Externally-funded R&D Percentage (as a % of 1.)							
2. Capital Expenditures								
E.	1. On a scale of 1 to 10, estimate your organization's overall financial health (1 being imminent failure and 10 being highly profitable for the foreseeable future).							
Comments:								
BUSINESS CONFIDENTIAL - Per Section 705(d) of the Defense Production Act								

Data Confirmation
2024 Net Sales
\$0

Previous Page		14. Business Challenges				Next Page	
<p>Identify the issues that have impacted your U.S. operations from 2019 to 2024, and the issues that you anticipate will impact your organization between 2025 and 2030. Next, rank your organization's top five issues for both time frames (1 being the most important issue; 2 being the next most important issue, etc.).</p> <p>Explain your organization's experienced or expected issues where examples and narrative will aid the U.S. Government's understanding of your concerns and provide any suggestions for ways the U.S. Government (USG) can help mitigate these issues.</p>							
	Type of Issue	2019 to 2024		2025 to 2030		Explanation of Issue	Suggested USG Solution/Mitigation
		-Yes/No-	Rank	-Yes/No-	Rank		
	Aging equipment, facilities, or infrastructure						
	Aging workforce						
	Competition - domestic						
	Competition - foreign						
	Counterfeit parts and materials						
	Cybersecurity						
	Environmental regulations/remediation						
	Export controls (EAR/ITAR)						
	Financing/credit availability						
	U.S. Government acquisition process						
	U.S. Government regulatory burden						
	Healthcare costs						
	Industrial espionage - domestic						
	Industrial espionage - foreign						
	Input availability (e.g., materials)						
A	Input cost						
	Input quality						
	Intellectual property/patent infringement						
	Training/Retaining Skilled Labor						
	Labor availability/costs						
	Lack of infrastructure						
	Lack of public R&D partnerships (e.g., universities)						
	Natural disasters (including disease/quarantine)						
	Obsolescence						
	Per- and poly- fluoroalkyl substances (PFAS) regulations						
	Proximity to customers						
	Proximity to suppliers						
	Quality assurance						
	R&D costs						
	Reduction in/Lack of U.S. demand						
	Taxes and Tariffs						
	Trade disputes						
	Worker/skills retention						
	Other						
	Other						
Respond to the following questions related to regulatory issues that are impacting your organization's operations.							
1.	Are environmental regulations inhibiting your organization from constructing, expanding, or modernizing any of its facilities in the United States?						
	If yes, please explain:						
2.	Are quality regulations inhibiting your organization from constructing, expanding, or modernizing any of its facilities in the United States?						
	If yes, please explain:						
B. 3.	What U.S. regulations, if any, inhibit your organization from researching, developing, or implementing new manufacturing processes?						
4.	What can the U.S. government do to promote the manufacture of your APIs or starting materials in the United States?						
5.	More generally, how could the U.S. government help your organization improve its long-term competitiveness in the United States?						
Additional Comments:							
BUSINESS CONFIDENTIAL - Per Section 705(d) of the Defense Production Act							

[Previous Page](#)**15. Certification**

The undersigned certifies that the information herein supplied in response to this questionnaire is complete and correct to the best of his/her knowledge. It is a criminal offense to willfully make a false statement or representation to any department or agency of the United States government as to any matter within its jurisdiction (18 U.S.C. 1001).

Once this survey is complete, first save it to your computer, and then submit the document via email to the address below:

APIsurvey@bis.doc.gov

Organization Name	
Organization's Internet Address	
Name of Authorizing Official	
Title of Authorizing Official	
E-mail Address of Authorizing Official	
Phone Number and Extension of Authorizing Official	
Date Certified	
In the box, provide any additional comments or any other information you wish to include regarding this survey assessment.	
How many hours did it take to complete this survey?	
BUSINESS CONFIDENTIAL - Per Section 705(d) of the Defense Production Act	