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OFFICE OF MANAGEMENT AND BUDGET

Request for Information; Domestic and Near Shore Manufacturing of Essential Medicines on the ASPR 86 List

AGENCY: Office of Management and Budget

ACTION: Request for information.

SUMMARY: The Office of Management and Budget (OMB) is conducting market research to identify new and unused (idle) domestic, U.S.-based, and near shore production capabilities for Finished Dose Forms (FDF), Active Pharmaceutical Ingredients (API), and Key Starting Materials (KSM) associated with the Administration for Strategic Preparedness and Response (ASPR) 86 list of essential medicines. Responses will be shared with federal agencies that have requirements for essential medicines or responsibilities for strengthening the domestic industrial base for essential generic pharmaceuticals.

DATES: Responses to this request for information will be accepted for consideration until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Responses must be submitted electronically through *regulations.gov.* Mailed paper submissions will not be accepted, and electronic submissions received after the deadline may not be considered.

Instructions: Federal eRulemaking Portal: Go to *www.regulations.gov* search "Domestic and Near Shore Manufacturing of Essential Medicines RFI" to submit your comments electronically. Information on how to use *Regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under "FAQ" (*https://www.regulations.gov/faq*). Should you choose to include proprietary information or confidential business information in your submission, please ensure you use appropriate markings and handling instructions to alert OMB as to the nature of information being submitted

and maintain proper handling. Your response will be shared with other Federal agencies and entities.

Privacy Act Statement: OMB is issuing this request for information (RFI) pursuant to its authorities under 31 U.S.C. § 501 et seq. Comments and commenter information are maintained under the OMB Public Input System of Records, OMB/INPUT/01. The system of records notice accessible at 88 FR 20913 (*https://www.federalregister.gov/documents/2023/04/07/2023-07452/privacy-act-of-1974-system-of-records*) includes a list of routine uses associated with the collection of this information.

Disclaimer: Participation in this RFI is strictly voluntary. OMB will use your feedback to inform sound decision-making on topics related to this RFI regarding potential government-wide actions to revitalize the domestic manufacturing base, create new opportunities for U.S. firms and workers, and position U.S. businesses to compete and lead globally in strategic industries. This announcement should not be construed as a commitment of any kind by the U.S. Government. The U.S. Government is in no way liable to pay for or reimburse any companies or entities that respond to this announcement. Nothing in this announcement constitutes an obligation on the part of the U.S. Government. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed.

FOR FURTHER INFORMATION CONTACT: Please direct questions regarding this Notice to Robert Orr, Deputy to the Associate Director of Economic Policy, Office of Management and Budget, tel: 202-395-1390, or email the Made in America Office at *MadeInAmerica@omb.eop.gov* with "Domestic and Near Shore Manufacturing of Essential Medicines on the ASPR 86 List" in the subject line.

SUPPLEMENTARY INFORMATION:

1. Executive Summary

OMB is conducting market research to identify new and idle domestic, U.S.-based, and near shore production capabilities for FDF, APIs, and KSMs associated with the ASPR 86 list of

essential medicines. The list is provided as an attachment to this RFI. OMB is also seeking equivalent information on the following antibiotics which are not on the ASPR 86 list: Amoxicillin and Ciprofloxacin, due to potential supply chain vulnerabilities. This RFI is open to participation from all entities that are not Foreign Entities of Concern (FEOC). For purposes of this RFI, FEOC means a person owned by, controlled by, or subject to the jurisdiction or direction of a government of China, Russia, Iran, or North Korea.

Information is requested from qualified manufacturers within the pharmaceutical, chemical, and petrochemical sectors. Responses will be shared with federal agencies that have requirements for essential medicines or responsibilities for strengthening the domestic industrial base for essential generic pharmaceuticals. Feedback may be used to help inform near-term federal acquisition efforts (both enterprise and government-wide), which might include limiting competition for a federal contract to a particular source or sources to achieve industrial mobilization, and related efforts to inform potential sources of financial assistance.

2. Background

This RFI is driven by the urgent need to ensure domestic and near shore production of pharmaceutical products for the American people as a matter of national security. The initiative directly supports the established objective to secure the domestic production of the essential medicines, and their precursors, listed in the ASPR 86 list in eighteen months. And to reduce or eliminate dependence on medicines produced by FEOCs.

Most essential medicine APIs are not made domestically, leaving the country vulnerable to foreign supply disruptions, especially from adversarial nations. A majority of KSMs needed to produce generic medicines are not manufactured in the United States.

This RFI is seeks information both to optimize use of existing domestic or near shore capacity and to better understand ongoing or planned actions to create new domestic or near shore capacity for essential generic pharmaceuticals on the ASPR 86 list. Schedule 2 Controlled substances and branded drugs on the ASPR 86 list are not priorities for this RFI.

3. Statement of Need

The primary objective is to identify existing and new domestic, U.S.-based or near shore production capabilities for FDFs, APIs, and KSMs associated with the ASPR 86 list of essential medicines. We are seeking information on all aspects of the manufacturing lifecycle, from raw material sourcing to finished product. This information will be used to shape federal policies, programs and potential partnerships to re-shore production and eliminate supply chain risks.

4. Data Availability

To facilitate a comprehensive assessment of market opportunities to leverage existing or new capabilities, the Government intends to provide qualified respondents with access to historical federal spend data related to the essential medicines categorized under the ASPR 86 list and a comprehensive list of associated APIs and KSMs. Access protocols and confidentiality requirements for this data will be distributed to interested parties upon request.

5. Feedback

a. Entity overview

If your entity has idle capacity or is planning new capacity to produce FDFs, APIs, or KSMs on the ASPR 86 list domestically or at a near shore location, please provide the following information:

i. legal entity name.

ii. headquarters location.

iii. unique entity identifier, if registered in the System for Award Management.

b. Feasibility Feedback – Idle Capacity

If your entity has idle capacity to produce FDFs, APIs, or KSMs on the ASPR 86 list domestically or at a near shore location, please provide and the following information, broken out by FDF, API, and KSM:

i. *Identifier:* Molecule name, description, national drug code.

ii. *Manufacturing site*: Location of existing site.

iii. *Available capacity*: Amount of current production, amount of unused capacity and estimated timeline to reach full operational capacity.

iv. *Regulatory compliance*: Current FDA registration status for each molecule/NDC.

v. *Technical capabilities*: Confirmation of FDF, API, and KSM synthesis or formulation capabilities relevant to the ASPR 86 list.

vi. *Sourcing strategies*: Supply chain mapping for upstream inputs, including specific countries of origin.

vii. *Required demand:* Price per unit needed to operate at full capacity.

viii. *Financing*: A description of financing that may be sought to fill or increase production – debt, equity, offtake contract, other. Reason for financing (e.g., restart cost, additional labor).

ix. *Cost considerations*: Industry perspectives on key cost drivers.

4.3. Feasibility Feedback – New Capacity

If your entity is actively planning to domestically produce FDFs, APIs, or KSMs on the ASPR 86 list domestically or at a near shore location, please provide the following information broken out by FDF, API, and KSM:

i. *Identifier*: Molecule name, description, national drug code.

ii. *Manufacturing site*: Location of existing or planned site for new production.

iii. *Facility status*: Identify if site is existing, brownfield, or greenfield. If not existing, identify if funding has been secured for construction and/or renovation.

iv. *Anticipated capacity*: Level of planned production.

v. *Required demand*: Level of demand and projected cost per unit needed to produce the product and maintain long-term domestic viability.

vi. *Regulatory compliance*: Current FDA registration status.

vii. *Technical capabilities*: Confirmation of FDF, API, and KSM synthesis or formulation capabilities relevant to the ASPR 86 list.

viii. *Sourcing strategies*: Supply chain mapping for upstream inputs, including specific countries of origin.

ix. *Financing*: A description of financing that may be sought to establish new production – debt, equity, offtake contract, other. Reason for financing (e.g., restart cost, additional labor).

x. *Cost considerations*: Industry perspectives on key cost drivers.

Michael Stumo,
Director,
Made in America Office.

ASPR 86 List of Essential Medicines

#	ASPR medicine	API / drug substance	KSM or critical upstream input
1	Acetaminophen	Acetaminophen	**4 aminophenol**
2	Acyclovir	Acyclovir	**Purine starting material, commonly 2 amino 6 chloropurine, plus protected hydroxyethoxymethyl side chain precursor**; route specific
3	Adenosine	Adenosine	**Adenine plus D ribose**, or fermentation derived nucleoside intermediate depending process
4	Albuterol	Albuterol, usually albuterol sulfate	**Substituted salicylaldehyde / acetophenone aromatic precursor carrying the salbutamol carbon skeleton**; regulatory KSM is route specific
5	Alteplase	Alteplase	**Recombinant production cell bank and cell culture inputs**; conventional small molecule KSM designation is not applicable
6	Amiodarone	Amiodarone	**2 butylbenzofuran intermediate plus iodinated benzoyl / phenoxy precursor**; route specific
7	Ampicillin	Ampicillin	**6 aminopenicillanic acid, 6 APA**, plus D phenylglycine derivative
8	Apixaban	Apixaban	**Lactam / pyrazole aryl intermediates used to assemble the apixaban scaffold**; regulatory KSM is route specific
9	Argatroban	Argatroban	**Protected L arginine derivative plus tetrahydroquinoline carboxylic acid intermediate**
10	Aspirin	Acetylsalicylic acid	**Salicylic acid**
11	Atropine	Atropine	**Tropine plus tropic acid**
12	Azithromycin	Azithromycin	**Erythromycin A**
13	Bictegravir / Emtricitabine / Tenofovir alafenamide	Bictegravir; emtricitabine; tenofovir alafenamide	**Three independent API supply chains.** Bictegravir intermediates are route specific; emtricitabine uses fluorinated cytosine / oxathiolane intermediates; TAF derives from **tenofovir / PMPA related phosphonate intermediate**
14	Calcium gluconate	Calcium gluconate	**Gluconic acid or gluconate plus pharmaceutical grade calcium source**
15	Cefepime	Cefepime	**7 aminocephalosporanic acid, 7 ACA, derived cephalosporin nucleus** plus aminothiazolyl oxime side chain
16	Ceftazidime / Avibactam	Ceftazidime; avibactam	Ceftazidime: **7 ACA derived nucleus plus aminothiazolyl oxime side chain**. Avibactam: synthetic bicyclic / diazabicyclooctane intermediates; route specific
17	Ceftriaxone	Ceftriaxone	**7 ACA derived cephalosporin nucleus plus aminothiazolyl methoxyimino side chain**
18	Chlorhexidine	Chlorhexidine	**Hexamethylenediamine and chlorophenyl biguanide precursor chemistry**
19	Continuous renal replacement solution	Electrolyte solution, multiple ingredients	**Sodium chloride, potassium chloride where used, calcium chloride, magnesium chloride, sodium bicarbonate or lactate, glucose**; this is a formulation rather than a single API
20	Dantrolene	Dantrolene	**5 nitro 2 furaldehyde plus aminophenyl hydantoin intermediate**
21	Daptomycin	Daptomycin	**Fermentation organism / production cell bank and fermentation feedstocks**; no single conventional synthetic KSM

22	Dexamethasone	Dexamethasone	**Advanced corticosteroid nucleus intermediate** derived from steroid feedstock; precise KSM is process specific
23	Dextrose 50% injection	Dextrose	**Pharmaceutical grade glucose / dextrose**, generally derived from starch hydrolysate
24	Diltiazem	Diltiazem	**Chiral substituted glycidate / epoxide plus 2 aminothiophenol derived intermediate**
25	Diphenhydramine	Diphenhydramine	**Benzhydryl chloride or benzhydrol plus 2 dimethylaminoethanol**
26	Dobutamine	Dobutamine	**Catechol phenethylamine and substituted phenylalkyl intermediates**; route specific
27	Doxycycline	Doxycycline	**Oxytetracycline**, fermentation derived
28	Enoxaparin	Enoxaparin sodium	**Unfractionated porcine intestinal mucosal heparin**
29	Epinephrine	Epinephrine	**Catechol derived adrenalone / amino ketone intermediate**
30	Etomidate	Etomidate	**Substituted imidazole carboxylate and chiral phenethyl precursor**; route specific
31	Fentanyl	Fentanyl	**N phenethyl 4 piperidone, NPP**, with aniline in the classic route
32	Fluconazole	Fluconazole	**2,4 difluoroaryl carbonyl intermediate plus 1,2,4 triazole**
33	Furosemide	Furosemide	**2,4 dichloro 5 sulfamoylbenzoic acid plus furfurylamine**
34	Haloperidol	Haloperidol	**4 chlorophenyl hydroxypiperidine intermediate plus fluorobutyrophenone intermediate**
35	Heparin	Heparin sodium	**Porcine intestinal mucosa / crude heparin**
36	Hydralazine	Hydralazine	**1 chlorophthalazine plus hydrazine**
37	Hydromorphone	Hydromorphone	**Morphine or thebaine derived opiate intermediate**, depending route
38	Ibuprofen	Ibuprofen	**Isobutylbenzene**
39	Immune globulin	Human immune globulin	**Human plasma**; no small molecule KSM
40	Insulin regular	Human insulin	**Recombinant microbial cell bank plus fermentation inputs**; no conventional chemical KSM
41	Intralipid 20%	Soybean oil lipid emulsion	**Purified soybean oil, egg phospholipids, glycerol**
42	Ipratropium bromide	Ipratropium bromide	**Atropine / tropane intermediate**, followed by N isopropyl quaternization
43	Isoflurane	Isoflurane	**Halogenated ether precursor**; exact regulatory starting material depends on fluorination / chlorination route
44	Labetalol	Labetalol	**Substituted salicylamide / acetophenone intermediate plus benzylamine fragment**; route specific
45	Lactulose	Lactulose	**Lactose**
46	Levetiracetam	Levetiracetam	**S 2 aminobutanamide derivative plus 4 halobutyryl precursor**
47	Levofloxacin	Levofloxacin	**Chiral fluorinated quinolone intermediate**; KSM designation is route specific
48	Levothyroxine	Levothyroxine sodium	**Iodinated L tyrosine intermediates, including diiodotyrosine derived material**
49	Lidocaine / Epinephrine	Lidocaine; epinephrine	Lidocaine: **2,6 dimethylaniline plus chloroacetyl intermediate and diethylamine**. Epinephrine: catechol derived adrenalone intermediate
50	Linezolid	Linezolid	**Fluoro morpholinyl aniline intermediate plus oxazolidinone side chain precursor**
51	Lorazepam	Lorazepam	**2 amino 2',5 dichlorobenzophenone derived benzodiazepine intermediate**

52	Magnesium sulfate	Magnesium sulfate	**Magnesium mineral / magnesium oxide or hydroxide plus sulfuric acid**
53	Meropenem	Meropenem	**Protected carbapenem 4 AA nucleus plus pyrrolidinylthio side chain intermediate**
54	Methylprednisolone	Methylprednisolone	**Advanced corticosteroid / pregnane nucleus intermediate**; precise KSM depends on synthetic route
55	Metoprolol	Metoprolol	**4 (2 methoxyethyl)phenol plus epichlorohydrin**, followed by isopropylamine
56	Metronidazole	Metronidazole	**2 methyl 5 nitroimidazole plus hydroxyethylating precursor**
57	Micafungin	Micafungin sodium	**FR901379 fermentation derived echinocandin intermediate**, followed by semisynthetic side chain modification
58	Midazolam	Midazolam	**Halogenated amino benzophenone / benzodiazepine ring precursor**; route specific
59	Morphine	Morphine sulfate / morphine	**Poppy straw concentrate / opium derived morphine alkaloid stream**
60	Naloxone	Naloxone	**Thebaine / oxymorphone derived opiate intermediate**
61	Nitroglycerin	Nitroglycerin	**Glycerol plus nitric acid**, with sulfuric acid process chemistry
62	Norepinephrine	Norepinephrine	**Catechol derived amino alcohol / amino ketone intermediate**
63	Ondansetron	Ondansetron	**Carbazolone / carbazole intermediate plus imidazole containing side chain precursor**; route specific
64	Oxytocin	Oxytocin	**Protected amino acids and peptide fragments used in solid phase or solution peptide synthesis**
65	Pantoprazole	Pantoprazole	**2 mercapto 5 difluoromethoxybenzimidazole plus substituted chloromethyl pyridine intermediate**
66	Penicillin G	Benzylpenicillin	**Fermentation organism plus phenylacetic acid side chain feedstock**
67	Phenylephrine	Phenylephrine	**3 hydroxy substituted acetophenone / amino alcohol precursor**; route specific
68	Phenytoin	Phenytoin	**Benzil plus urea**
69	Piperacillin / Tazobactam	Piperacillin; tazobactam	Piperacillin: **6 APA derived penicillin nucleus / ampicillin intermediate plus dioxopiperazine side chain**. Tazobactam: **penicillanic acid / 6 APA derived beta lactam nucleus**
70	Potassium chloride	Potassium chloride	**Potassium mineral brine / potash derived KCl**; no synthetic KSM in the conventional API sense
71	Propofol	Propofol	**Phenol plus propylene / isopropylating feedstock** to produce 2,6 diisopropylphenol
72	Rocuronium	Rocuronium bromide	**Steroidal androstane nucleus intermediate**; exact KSM is route specific
73	Sodium bicarbonate injection	Sodium bicarbonate	**Sodium carbonate plus carbon dioxide**, or equivalent bicarbonate production process
74	Sodium phosphate	Sodium phosphate salts	**Phosphoric acid plus sodium hydroxide / sodium carbonate**
75	Succinylcholine	Succinylcholine chloride	**Succinic acid / succinyl chloride derivative plus choline**
76	Surfactant	Pulmonary surfactant	**Product dependent:** animal lung extract and phospholipids for animal derived products; defined phospholipids and peptide components for synthetic products

77	Tacrolimus	Tacrolimus	**Streptomyces production strain, fermentation media, and downstream fermentation intermediate**
78	Thiamine	Thiamine	**Substituted pyrimidine intermediate plus thiazole intermediate**
79	Ticagrelor	Ticagrelor	**Triazolotriazine core intermediate plus chiral difluorophenyl cyclopentane fragment**; route specific
80	Topical / surface alcohol based sanitizers	Ethanol and/or isopropyl alcohol	**Ethanol or isopropanol feedstock**
81	Trimethoprim / Sulfamethoxazole	Trimethoprim; sulfamethoxazole	Trimethoprim: **3,4,5 trimethoxybenzaldehyde derived intermediate**. Sulfamethoxazole: **sulfonyl chloride aromatic intermediate plus 3 amino 5 methylisoxazole**
82	Valganciclovir	Valganciclovir	**Ganciclovir plus protected L valine derivative**
83	Vancomycin	Vancomycin	**Amycolatopsis production strain and fermentation inputs**
84	Vasopressin	Vasopressin	**Protected amino acids / peptide fragments** used in peptide synthesis
85	Vitamin K	Phytonadione, vitamin K1	**2 methyl 1,4 naphthoquinone / menadione related intermediate plus phytol side chain**
86	Voriconazole	Voriconazole	**Fluoropyrimidine / triazole containing chiral intermediates**; precise KSM is route specific

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