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May 7, 2025

The Honorable Howard W. Lutnick
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Avenue N.W.
Washington, DC 20230

PUBLIC VERSION

Attn: Eric Longnecker, Stephen Astle

Submitted via [Regulations.gov](#)

Re: BIS-2025-0022; XRIN 0694-XC120; Comments of Corning Pharmaceutical Glass on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Secretary Lutnick:

On behalf of Corning Pharmaceutical Glass, LLC (“CPG”) – a subsidiary of Corning Incorporated – we submit the following comments concerning the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. These comments respond to the Notice published in the Federal Register by the Bureau of Industry and Security (“BIS”) on April 16, 2025, and are timely filed pursuant to the May 7, 2025 deadline established in that notice.¹

CPG is a leading U.S. manufacturer of critical materials for the pharmaceuticals industry, with headquarters in Corning, New York and production facilities located throughout the United States.² Specifically, CPG manufactures high-quality glass articles that are ultimately used for the storage, conveyance, distribution, and administration of medications and vaccines. As a fully integrated domestic producer, CPG employs more than 300 hardworking and dedicated U.S. workers, and manufactures a broad spectrum of pharmaceutical glass products. These include

¹ See Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, 90 Fed. Reg. 15,951 (BIS Apr. 16, 2025) (“Notice”).

² CPG manufactures finished pharmaceutical packaging at its Durham, North Carolina facility and intermediate pharmaceutical tubing at its Vineland, New Jersey facility. CPG also engages in research and development operations at its Erwin, New York facility.

both finished pharmaceutical packaging – such as cartridges, syringes, and vials – and the intermediate pharmaceutical tubing used in the fabrication of those articles. [

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Over the past decade, CPG has undertaken substantial capital investments to increase its capacity to produce pharmaceutical glass in the United States. As discussed in detail below, CPG was an active participant in Operation Warp Speed, and quickly ramped up production of pharmaceutical glass to meet increased demand during the COVID-19 pandemic. [

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I. Background Information on Pharmaceutical Glass

A. Pharmaceutical Tubing

Pharmaceutical tubing is an intermediate product specifically designed for use in pharmaceutical packaging. It is manufactured by melting a wide range of constituent elements at extremely high temperatures, forming the molten material into a long hollow tube as it cools, and then cutting the resultant tube to discrete lengths. Pharmaceutical tubing generally consists of Type I glass, which is renowned for its hydrolytic resistance – or its ability to withstand corrosion when in contact with water. Compositions that qualify as Type I glass include borosilicate glass (which consists primarily of silicon and boron) and aluminosilicate glass (which consists primarily of silicon and aluminum oxide with no boron).

The production process for pharmaceutical tubing is extremely capital-intensive. As a threshold matter, the furnaces used to melt the glass must be completely rebuilt every three to five years in order to ensure product quality and employee safety. Keeping the manufacturing facilities in working condition on a day-to-day basis also requires continuous investment and regular maintenance. Once idled, a furnace cannot be restarted without several months of work

and millions of dollars in expenditures. The production of pharmaceutical tubing consumes large amounts of energy and raw materials, meaning that manufacturers must be able to earn a reasonable return on their investments in order to continue to operate their facilities.

Pharmaceutical tubing is currently classified under the following eight-digit Harmonized Tariff Schedule of the United States subheadings³:

- 7002.32.00 – the provision for “Glass in balls . . . , rods or tubes, unworked: . . . Tubes: . . . Of other glass . . . ”
General Rate of Duty: 6.0 percent ad valorem
- 7002.39.00 - the provision for “Glass in balls . . . , rods or tubes, unworked: . . . Tubes: . . . Other: . . . ”
General Rate of Duty: 6.0 percent ad valorem

B. Pharmaceutical Packaging

Pharmaceutical packaging is a finished product fabricated from a pharmaceutical tubing input. It is manufactured by bending and cutting the tube into predetermined shapes and sizes, thus forming the package that will contain the medicine. Optional steps include chemical strengthening to further confer strength and durability, and/or applying coatings to the resultant product to enhance its resistance to damage and allow for faster fill / finish speeds. There are four general categories of pharmaceutical packaging: (i) ampoules (single dose and hermetically sealed), (ii) cartridges (variable dose with controlled volume), (iii) syringes (single dose with controlled volume), and (iv) vials (variable dose with rubber stopper or aluminum seal), with vials being the dominant format in the United States. Pharmaceutical packaging may be produced with clear glass, or with amber glass to provide additional protection from ultraviolet light, as shown below.

³ See Attachment 1 hereto.

Figure 1 – A Selection of Pharmaceutical Packaging



Pharmaceutical packaging has several characteristics that make it suitable for use in the storage, conveyance, distribution, and administration of medications and vaccines. It is hermetic and airtight, which ensures that the enclosed product is kept sterile and is not exposed to external elements. Pharmaceutical packaging is resistant to breakage under pressure and cracking at lower temperatures, and does not degrade throughout the cold chain process. It is chemically durable, meaning that it can withstand a variety of adverse storage conditions depending on its underlying composition.

The U.S. Food and Drug Administration (“FDA”) maintains stringent standards for pharmaceutical packaging that is in direct contact with – and may chemically react with – the medications and vaccines at issue.⁴ Specifically, the FDA “mandates the need for adequate information related to packaging materials,” including “a full description of the methods used in, and the facilities and controls used for, the packaging of drugs.”⁵ The FDA also recognizes that injectables “represent one of the highest risk drug products,” as the “potential effects of packaging component/dosage form interactions are numerous.”⁶ As such, pharmaceutical packaging “require{s} protection from microbial contamination . . . and may also need to be protected from light or exposure to gases.”⁷

⁴ See Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics (FDA May 1999) (as appended in **Attachment 2** hereto).

⁵ See id. at 2

⁶ See id. at 23-24.

⁷ See id. at 24.

Pharmaceutical packaging is currently classified under the following eight-digit Harmonized Tariff Schedule of the United States subheadings⁸:

- 7010.10.00 – the provision for “Carboys, bottles, flasks, jars, pots, vials, ampoules and other containers, of glass, of a kind used for the conveyance or packing of goods; preserving jars of glass; stoppers, lids and other closures, of glass: Ampoules”
General Rate of Duty: Free
- 7010.90.05 – the provision for “Carboys, bottles, flasks, jars, pots, vials, ampoules and other containers, of glass, of a kind used for the conveyance or packing of goods; preserving jars of glass; stoppers, lids and other closures, of glass: . . . Other: Serum bottles, vials and other pharmaceutical containers”
General Rate of Duty: Free
- 7017.90.50 – the provision for “Laboratory, hygienic or pharmaceutical glassware, whether or not graduated or calibrated: . . . Other: . . . Other”
General Rate of Duty: 6.7 percent ad valorem
- 9018.31.00 – the provision for “Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments; parts and accessories thereof: . . . Syringes, needles, catheters, cannulae and the like; parts and accessories thereof: Syringes, with or without needles; marts and accessories thereof”
General Rate of Duty: Free

II. Conditions of Competition

A. Demand for Pharmaceutical Glass Has Normalized Since the COVID-19 Pandemic

Demand for pharmaceutical glass in the United States has been extremely volatile over the past six years. [

⁸ See Attachment 3 hereto.

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B. [

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C. [

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Even prior to the COVID-19 pandemic, CPG engaged in substantial capital investments to enhance its U.S. production operations. In July 2017, CPG joined Merck and Pfizer at the White House to announce the development of Corning Valor Glass, a revolutionary pharmaceutical packaging product featuring enhanced strength and improved durability.⁹ While introducing this product, CPG committed to an initial investment of \$500 million to support future domestic manufacturing operations, as well as to the creation of 1,000 new jobs in the United States.¹⁰

In June 2020, CPG revealed that it would receive \$204 million from the Biomedical Advanced Research and Development Authority (“BARDA”) as part of Operation Warp Speed.¹¹ The BARDA grant assisted CPG in expanding its capacity to produce Corning Valor Glass and provide priority access to COVID-19 vaccine manufacturers.¹² In September 2022, CPG disclosed

⁹ See Attachment 4 hereto.

¹⁰ See id.

¹¹ See Attachment 5 hereto.

¹² See id.

that it would receive an addition \$104 million in funding from BARDA, allowing it to further expand production capacity for pharmaceutical tubing and pharmaceutical packaging.¹³

[

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III. [

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IV. Conclusion

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¹³ See Attachment 6 hereto.

] CPG is a large U.S. employer, a proud partner of the U.S. government, and has invested hundreds of millions of dollars in its domestic operations. [

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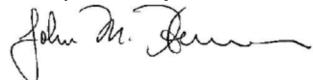
V. Request for Confidential Treatment

Pursuant to 15 C.F.R. § 705.6(a)(2), CPG requests confidential treatment of information enclosed in square brackets ([]) on pages 2, 5, 6, 7, and 8. The business confidential information contained on pages 5, 6, and 7 includes highly sensitive commercial and financial information on CPG's production capacity and levels of investment, as well as proprietary market intelligence obtained by CPG. This type of information is not available to the public and its release would cause substantial harm to the competitive position of CPG. This type of information is exempted from public disclosure by the Freedom of Information Act at 5 U.S.C. § 552(b)(4). A public version of these comments with business confidential information redacted is being submitted concurrently with this business confidential version.

* * *

We appreciate the Bureau of Industry and Security's considerations of these comments. If we can be of assistance in providing any additional information that might be helpful to the agency's investigation, please do not hesitate to contact us.

Respectfully submitted,



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Attachments

ATTACHMENT 1

Harmonized Tariff Schedule of the United States Revision 11 (2025)

Annotated for Statistical Reporting Purposes

CHAPTER 70

GLASS AND GLASSWARE

XIII
70-1

Notes

1. This chapter does not cover:
 - (a) Goods of heading 3207 (for example, vitrifiable enamels and glazes, glass frit, other glass in the form of powder, granules or flakes);
 - (b) Articles of chapter 71 (for example, imitation jewelry);
 - (c) Optical fiber cables of heading 8544, electrical insulators (heading 8546) or fittings of insulating material of heading 8547;
 - (d) Front windscreens (windshields), rear windows and other windows, framed, for vehicles of chapters 86 to 88;
 - (e) Front windscreens (windshields), rear windows and other windows, whether or not framed, incorporating heating devices or other electrical or electronic devices, for vehicles of chapters 86 to 88;
 - (f) Optical fibers, optically worked optical elements, hypodermic syringes, artificial eyes, thermometers, barometers, hydrometers or other articles of chapter 90;
 - (g) Luminaires or lighting fittings, illuminated signs, illuminated name-plates or the like, having a permanently fixed light source, or parts thereof of heading 9405;
 - (h) Toys, games, sports equipment, Christmas tree ornaments or other articles of chapter 95 (excluding glass eyes without mechanisms for dolls or for other articles of chapter 95); or
 - (ij) Buttons, fitted vacuum flasks, scent or similar sprays or other articles of chapter 96.
2. For the purposes of headings 7003, 7004 and 7005:
 - (a) Glass is not regarded as "worked" by reason of any process it has undergone before annealing;
 - (b) Cutting to shape does not affect the classification of glass in sheets;
 - (c) The expression "absorbent, reflecting or non-reflecting layer" means a microscopically thin coating of metal or of a chemical compound (for example, metal oxide) which absorbs, for example, infrared light; or which improves the reflecting qualities of the glass while still allowing it to retain a degree of transparency or translucency; or which prevents light from being reflected on the surface of the glass.
3. The products referred to in heading 7006 remain classified in that heading whether or not they have the character of articles.
4. For the purposes of heading 7019, the expression "glass wool" means:
 - (a) Mineral wools with a silica (SiO_2) content not less than 60 percent by weight;
 - (b) Mineral wools with a silica (SiO_2) content less than 60 percent but with an alkaline oxide (K_2O or Na_2O) content exceeding 5 percent by weight or a borax oxide (B_2O_3) content exceeding 2 percent by weight.

Mineral wools which do not comply with the above specifications fall in heading 6806.
5. Throughout the tariff schedule, the expression "glass" includes fused quartz and other fused silica.

Subheading Note

1. For the purposes of subheadings 7013.22, 7013.33, 7013.41 and 7013.91, the expression "lead crystal" means only glass having a minimum lead monoxide (PbO) content by weight of 24 percent.

Harmonized Tariff Schedule of the United States Revision 11 (2025)

Annotated for Statistical Reporting Purposes

XIII
70-2

Additional U.S. Notes

1. For the purposes of this chapter, the term "fused quartz or other fused silica" means glass containing more than 95 percent silica by weight.
2. For the purposes of headings 7003 through 7005, the expression "colored throughout the mass" refers to glass that has a transmittance of normally incident light of less than 66 percent at one or more wavelengths from 400 to 700 millimicrons, inclusive, or a transmittance of less than 80 percent at one or more wavelengths from 525 to 575 millimicrons, inclusive, for glass 6 mm in thickness, or of the equivalent transmittances for any other thickness, provided that, in determining such light transmittances, the effect of surface irregularities or configurations, or of other surface treatment (except flashing applied prior to solidification) and the effect of wire netting within the glass, shall be eliminated.
3. For the purposes of headings 7003 and 7004, glass of the same size and thickness imported in any shipment in quantities over 4.6 m² shall be denied entry unless it is--
 - (a) Packed in units containing, as nearly as the particular size permits, 4.6 m², or multiples thereof; or
 - (b) Packed in units containing multiples of the number of sheets of the same size and thickness which would be contained in a unit if packed to contain, as nearly as such size permits, 4.6 or 9.3 m²; or
 - (c) Otherwise packed in a manner which conforms to the packing practices of the domestic glass industry as determined and published from time to time by the Secretary of the Treasury.
4. For the purposes of heading 7005, the expression "polished," as used with reference to glass, refers to glass one or both of the surfaces of which have been made smooth and glossy, in whole or in part, by abrasive or chemical means or by floating the glass over molten metal.
5. For the purposes of subheading 7018.10.20, the term "imitation precious or semiprecious stones" means glass made into shapes suitable for use in jewelry or for other ornamental purposes in a manner similar to natural gemstones, whether or not in imitation thereof, but does not include natural gemstones, synthetic gemstones, reconstructed natural gemstones or imitation pearls.

Statistical Notes

1. For the purposes of headings 7003 and 7004, in determining the surface area of cast or rolled glass having irregular surfaces (such as corrugated glass), superficial area shall be used.
2. For the purposes of statistical reporting numbers 7009.91.5091 and 7009.92.5091, "over-the-door mirrors" means mirrors designed to be affixed to a door or hung from the top of a door by means of hooks which are either attached to or packaged with such mirrors at the time of importation. Brackets or other hardware may also be attached to these mirrors or included in the packaging.

Harmonized Tariff Schedule of the United States Revision 11 (2025)

Annotated for Statistical Reporting Purposes

XIII
70-3

Heading/ Subheading	Stat. Suf- fix	Article Description	Unit of Quantity	Rates of Duty	
				1 General	2 Special
7001.00		Cullet and other waste and scrap of glass, excluding glass from cathode-ray tubes or other activated glass of heading 8549; glass in the mass: Glass in the mass:			
7001.00.10	00	Of fused quartz or other fused silica.....	kg.....	Free ^{1/}	30%
7001.00.20	00	Other.....	kg.....	3% ^{1/}	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 50%
7001.00.51	00	Other.....	kg.....	Free ^{1/}	10%
7002		Glass in balls (other than microspheres of heading 7018), rods or tubes, unworked:			
7002.10		Balls:			
7002.10.10	00	Not over 6 mm in diameter.....	kg.....	3.9% ^{1/}	Free (A+, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 60%
7002.10.20	00	Other.....	kg.....	Free ^{1/}	55%
7002.20		Rods:			
7002.20.10	00	Of fused quartz or other fused silica.....	kg.....	Free ^{2/}	40%
7002.20.50	00	Other.....	kg.....	6% ^{1/}	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 65%
		Tubes:			
7002.31.00	00	Of fused quartz or other fused silica.....	kg.....	Free ^{1/}	40%
7002.32.00	00	Of other glass having a linear coefficient of expansion not exceeding 5×10^{-6} per Kelvin within a temperature range of 0°C to 300°C.....	kg.....	6% ^{1/}	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 65%
7002.39.00		Other.....		6% ^{1/}	Free (A*, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 65%
	10	Of a length not exceeding 200 mm.....	No.		
	90	Other.....	kg		

Harmonized Tariff Schedule of the United States Revision 11 (2025)

Annotated for Statistical Reporting Purposes

XIII

Endnotes--page 70 - 42

1/ See 9903.88.03.

2/ See 9903.88.02.

3/ See 9903.88.69.

4/ See 9903.90.08.

5/ See 9903.88.15.

ATTACHMENT 2

Guidance for Industry

Container Closure Systems for Packaging Human Drugs and Biologics

CHEMISTRY, MANUFACTURING, AND CONTROLS DOCUMENTATION

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

May 1999

Guidance for Industry

Container Closure Systems for Packaging Human Drugs and Biologics

CHEMISTRY, MANUFACTURING, AND CONTROLS DOCUMENTATION

Additional copies are available from:

Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
Center for Drug Evaluation and Research (CDER)
5600 Fishers Lane
Rockville, Maryland 20857
(Tel) 301-827-4573
(Internet) <http://www.fda.gov/cder/guidance/index.htm>

or

Office of Communications
Training and Manufacturers Assistance, HFM-40
Center for Biologics Evaluation and Research (CBER)
1401 Rockville Pike
Rockville, Maryland 20852-1448
(Fax) 888-CBERFAX or 301-827-3844
(Voice Information) 800-835-4709 or 301-827-1800
(Internet) <http://www.fda.gov/cber/guidelines.htm>

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
May 1999**

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GUIDANCE FOR INDUSTRY¹

CONTAINER CLOSURE SYSTEMS FOR PACKAGING HUMAN DRUGS AND BIOLOGICS

CHEMISTRY, MANUFACTURING, AND CONTROLS DOCUMENTATION

I. INTRODUCTION

This document is intended to provide guidance on general principles² for submitting information on packaging materials used for human drugs and biologics.³ This guidance supersedes the FDA *Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics*, issued in February 1987 and the packaging policy statement issued in a letter to industry dated June 30, 1995 from the Office of Generic Drugs.⁴ This guidance is not intended to describe the information that should be provided about packaging operations associated with drug product manufacture.

Approaches which differ from those described in this guidance may be followed, but the applicant is encouraged to discuss significant variations in advance with the appropriate CDER chemistry review staff or CBER review staff. This is to prevent applicants or sponsors from spending unnecessary time and effort in preparing a submission that the FDA may later determine to be unacceptable.

¹ This guidance has been prepared by the Packaging Technical Committee of the Chemistry, Manufacturing, and Controls Coordinating Committee (CMC CC) in the Center for Drug Evaluation and Research (CDER) and in conjunction with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on container closure systems for the packaging of human drugs and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

² In general, this guidance does not suggest specific test methods and acceptance criteria (except for references to *The United States Pharmacopoeia* methods), nor does it suggest comprehensive lists of tests. These details should be determined based on good scientific principles for each specific container closure system for particular drug product formulations, dosage forms, and routes of administration. Acceptance criteria should be based on actual data for particular packaging components and container closure systems, and they should be set to ensure batch-to-batch uniformity of packaging components.

³ As used in this guidance, the terms *drug* and *drug product* include biologics unless otherwise noted.

⁴ The policy statement is a document titled *Container/Closure Information Which Should Be Provided In An ANDA/AADA* which was written by the Office of Generic Drugs/Packaging Advisory Group.

II. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (the Act) mandates the need for adequate information related to packaging materials. Section 501(a)(3) of the Act states that a drug is deemed to be adulterated "if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health...." In addition, section 502 of the Act states that a drug is considered misbranded if there are packaging omissions. Also, section 505 of the Act requires a full description of the methods used in, and the facilities and controls used for, the packaging of drugs (see Attachment A).

Section 505(b)(1)(D) of the Act states that an application shall include a full description of the methods used in, the manufacturing, processing and packing of such drug. This includes facilities and controls used in the packaging a drug product.

A. Definitions⁵

Materials of construction⁶ refer to the substances (e.g., glass, high density polyethylene (HDPE) resin, metal) used to manufacture a packaging component.

A packaging component means any single part of a container closure system. Typical components are containers (e.g., ampules, vials, bottles), container liners (e.g., tube liners), closures (e.g., screw caps, stoppers), closure liners, stopper overseals, container inner seals, administration ports (e.g., on large-volume parenterals (LVPs)), overwraps, administration accessories, and container labels. A *primary packaging component* means a packaging component that is or may be in direct contact with the dosage form. A *secondary packaging component* means a packaging component that is not and will not be in direct contact with the dosage form.

A container closure system refers to the sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug product. A *packaging system* is equivalent to a container closure system.

⁵ These definitions are intended to clarify the use of certain terms in this guidance only and are not intended to supersede the definitions of *container* and *package* as provided for in 21 CFR 600.3.

⁶ This term is used in a general sense for the basic material, which should be defined in the application in terms of its specific chemical composition for a given drug application (e.g., the specific polymer and any additives used to make the material).

D. Inhalation Drug Products

Inhalation drug products include inhalation aerosols (metered dose inhalers); inhalation solutions, suspensions, and sprays (administered via nebulizers); inhalation powders (dry powder inhalers); and nasal sprays. The CMC and preclinical considerations for inhalation drug products are unique in that these drug products are intended for respiratory-tract compromised patients. This is reflected in the level of concern given to the nature of the packaging components that may come in contact with the dosage form or the patient (see Table 1).

Guidance regarding the container closure system information to support the approval of applications for inhalation drug products will be provided in two guidance documents when finalized: the guidance for industry *Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing and Controls Documentation* (a draft was issued in October 1998) and the guidance for industry *Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products; Chemistry, Manufacturing and Controls Documentation*, which is currently under development.

E. Drug Products for Injection and Ophthalmic Drug Products

These dosage forms share the common attributes that they are generally solutions, emulsions, or suspensions, and are all required to be sterile. Injectable dosage forms represent one of the highest risk drug products (see Table 1). Any contaminants present (as a result of contact with a packaging component or due to the packaging system's failure to provide adequate protection) can be rapidly and completely introduced into the patient's general circulation. Although the risk factors associated with ophthalmics are generally considered to be lower than for injectables, any potential for causing harm to the eyes demands caution.

1. Injectable Drug Products

Injectable drug products may be liquids in the form of solutions, emulsions, suspensions, or dry solids that are to be combined with an appropriate vehicle to yield a solution or suspension. Injections are classified as small-volume parenterals (SVPs), if they have a solution volume of 100 mL or less, or as large-volume parenterals (LVPs), if the solution volume exceeds 100 mL.¹⁹ For solids that must be dissolved or dispersed in an appropriate diluent before being injected, the diluent may be in the same container closure system (e.g., a two-part vial) or be part of the same market package (e.g., a kit containing a vial of diluent).

¹⁹ The terms SVP and LVP as used in this guidance correspond to the definitions of small-volume injection and large-volume injection, respectively, in USP 23, page 1650.

An SVP may be packaged in a disposable cartridge, a disposable syringe, a vial, an ampule or a flexible bag. An LVP may be packaged in a vial, a flexible bag, a glass bottle or, in some cases, as a disposable syringe.

Cartridges, syringes, vials, and ampules are usually composed of Type I or II glass, or polypropylene. Flexible bags are typically constructed with multilayered plastic. Stoppers and septa in cartridges, syringes, and vials are typically composed of elastomeric materials. The input (medication) and output (administration) ports for flexible bags may be plastic and/or elastomeric materials. An overwrap may be used with flexible bags to retard solvent loss and to protect the flexible packaging system from rough handling.

The potential effects of packaging component/dosage form interactions are numerous. Hemolytic effects may result from a decrease in tonicity and pyrogenic effects may result from the presence of impurities. The potency of the drug product or concentration of the antimicrobial preservatives may decrease due to adsorption or absorption. A cosolvent system essential to the solubilization of a poorly soluble drug can also serve as a potent extractant of plastic additives. A disposable syringe may be made of plastic, glass, rubber, and metal components, and such multicomponent construction provides a potential for interaction that is greater than when a container consists of a single material.

Injectable drug products require protection from microbial contamination (loss of sterility or added bioburden) and may also need to be protected from light or exposure to gases (e.g., oxygen). Liquid-based injectables may need to be protected from solvent loss, while sterile powders or powders for injection may need to be protected from exposure to water vapor. For elastomeric components, data showing that a component meets the requirements of USP Elastomeric Closures for Injections will typically be considered sufficient evidence of safety. For plastic components, data from USP Biological Reactivity Tests will typically be considered sufficient evidence of safety. Whenever possible, the extraction studies should be performed using the drug product. If the extraction properties of the drug product vehicle may reasonably be expected to differ from that of water (e.g., due to high or low pH or due to a solubilizing excipient), then drug product should be used as the extracting medium. If the drug substance significantly affects extraction characteristics, it may be necessary to perform the extractions using the drug product vehicle. If the total of extracts significantly exceeds the amount obtained from water extraction, then an extraction profile should be obtained. It may be advisable to obtain a quantitative extraction profile of an elastomeric or plastic packaging component and to compare this periodically to the profile from a new batch of the packaging component. Extractables should be identified whenever possible. For a glass packaging component, data from USP Containers: Chemical Resistance — Glass Containers will typically be considered sufficient evidence of safety and compatibility. In some cases (e.g., for some chelating

ATTACHMENT 3

Harmonized Tariff Schedule of the United States Revision 11 (2025)

Annotated for Statistical Reporting Purposes

CHAPTER 70

GLASS AND GLASSWARE

XIII
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Notes

1. This chapter does not cover:
 - (a) Goods of heading 3207 (for example, vitrifiable enamels and glazes, glass frit, other glass in the form of powder, granules or flakes);
 - (b) Articles of chapter 71 (for example, imitation jewelry);
 - (c) Optical fiber cables of heading 8544, electrical insulators (heading 8546) or fittings of insulating material of heading 8547;
 - (d) Front windscreens (windshields), rear windows and other windows, framed, for vehicles of chapters 86 to 88;
 - (e) Front windscreens (windshields), rear windows and other windows, whether or not framed, incorporating heating devices or other electrical or electronic devices, for vehicles of chapters 86 to 88;
 - (f) Optical fibers, optically worked optical elements, hypodermic syringes, artificial eyes, thermometers, barometers, hydrometers or other articles of chapter 90;
 - (g) Luminaires or lighting fittings, illuminated signs, illuminated name-plates or the like, having a permanently fixed light source, or parts thereof of heading 9405;
 - (h) Toys, games, sports equipment, Christmas tree ornaments or other articles of chapter 95 (excluding glass eyes without mechanisms for dolls or for other articles of chapter 95); or
 - (ij) Buttons, fitted vacuum flasks, scent or similar sprays or other articles of chapter 96.
2. For the purposes of headings 7003, 7004 and 7005:
 - (a) Glass is not regarded as "worked" by reason of any process it has undergone before annealing;
 - (b) Cutting to shape does not affect the classification of glass in sheets;
 - (c) The expression "absorbent, reflecting or non-reflecting layer" means a microscopically thin coating of metal or of a chemical compound (for example, metal oxide) which absorbs, for example, infrared light; or which improves the reflecting qualities of the glass while still allowing it to retain a degree of transparency or translucency; or which prevents light from being reflected on the surface of the glass.
3. The products referred to in heading 7006 remain classified in that heading whether or not they have the character of articles.
4. For the purposes of heading 7019, the expression "glass wool" means:
 - (a) Mineral wools with a silica (SiO_2) content not less than 60 percent by weight;
 - (b) Mineral wools with a silica (SiO_2) content less than 60 percent but with an alkaline oxide (K_2O or Na_2O) content exceeding 5 percent by weight or a borax oxide (B_2O_3) content exceeding 2 percent by weight.

Mineral wools which do not comply with the above specifications fall in heading 6806.
5. Throughout the tariff schedule, the expression "glass" includes fused quartz and other fused silica.

Subheading Note

1. For the purposes of subheadings 7013.22, 7013.33, 7013.41 and 7013.91, the expression "lead crystal" means only glass having a minimum lead monoxide (PbO) content by weight of 24 percent.

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Additional U.S. Notes

1. For the purposes of this chapter, the term "fused quartz or other fused silica" means glass containing more than 95 percent silica by weight.
2. For the purposes of headings 7003 through 7005, the expression "colored throughout the mass" refers to glass that has a transmittance of normally incident light of less than 66 percent at one or more wavelengths from 400 to 700 millimicrons, inclusive, or a transmittance of less than 80 percent at one or more wavelengths from 525 to 575 millimicrons, inclusive, for glass 6 mm in thickness, or of the equivalent transmittances for any other thickness, provided that, in determining such light transmittances, the effect of surface irregularities or configurations, or of other surface treatment (except flashing applied prior to solidification) and the effect of wire netting within the glass, shall be eliminated.
3. For the purposes of headings 7003 and 7004, glass of the same size and thickness imported in any shipment in quantities over 4.6 m² shall be denied entry unless it is--
 - (a) Packed in units containing, as nearly as the particular size permits, 4.6 m², or multiples thereof; or
 - (b) Packed in units containing multiples of the number of sheets of the same size and thickness which would be contained in a unit if packed to contain, as nearly as such size permits, 4.6 or 9.3 m²; or
 - (c) Otherwise packed in a manner which conforms to the packing practices of the domestic glass industry as determined and published from time to time by the Secretary of the Treasury.
4. For the purposes of heading 7005, the expression "polished," as used with reference to glass, refers to glass one or both of the surfaces of which have been made smooth and glossy, in whole or in part, by abrasive or chemical means or by floating the glass over molten metal.
5. For the purposes of subheading 7018.10.20, the term "imitation precious or semiprecious stones" means glass made into shapes suitable for use in jewelry or for other ornamental purposes in a manner similar to natural gemstones, whether or not in imitation thereof, but does not include natural gemstones, synthetic gemstones, reconstructed natural gemstones or imitation pearls.

Statistical Notes

1. For the purposes of headings 7003 and 7004, in determining the surface area of cast or rolled glass having irregular surfaces (such as corrugated glass), superficial area shall be used.
2. For the purposes of statistical reporting numbers 7009.91.5091 and 7009.92.5091, "over-the-door mirrors" means mirrors designed to be affixed to a door or hung from the top of a door by means of hooks which are either attached to or packaged with such mirrors at the time of importation. Brackets or other hardware may also be attached to these mirrors or included in the packaging.

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Heading/ Subheading	Stat. Suf- fix	Article Description	Unit of Quantity	Rates of Duty		
				1		2
				General	Special	
7010		Carboys, bottles, flasks, jars, pots, vials, ampoules and other containers, of glass, of a kind used for the conveyance or packing of goods; preserving jars of glass; stoppers, lids and other closures, of glass:				
7010.10.00	00	Ampoules.....	gross.....	Free ¹¹		50¢/gross
7010.20		Stoppers, lids and other closures:				
7010.20.20	00	Produced by automatic machine.....	gross.....	2.5% ¹¹	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG)	25%
7010.20.30	00	Other.....	gross.....	5.2% ¹¹	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG)	75%
7010.90		Other:				
7010.90.05		Serum bottles, vials and other pharmaceutical containers.....		Free ¹¹		50¢/gross
	10	Of a capacity exceeding 1 liter.....	gross			
	20	Of a capacity exceeding 0.33 liter but not exceeding 1 liter.....	gross			
	30	Of a capacity exceeding 0.15 liter but not exceeding 0.33 liter.....	gross			
	40	Of a capacity not exceeding 0.15 liter.....	gross			
		Containers (with or without their closures) of a kind used for the conveyance or packing of perfume or other toilet preparations; other containers if fitted with or designed for use with ground glass stoppers:				
7010.90.20		Produced by automatic machine.....		2.5% ¹¹	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG)	25%
	10	Of a capacity exceeding 1 liter.....	gross			
	20	Of a capacity exceeding 0.33 liter but not exceeding 1 liter.....	gross			
	30	Of a capacity exceeding 0.15 liter but not exceeding 0.33 liter.....	gross			
	40	Of a capacity not exceeding 0.15 liter.....	gross			
7010.90.30		Other.....		5.2% ¹¹	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG)	75%
	10	Of a capacity exceeding 1 liter.....	gross			
	20	Of a capacity exceeding 0.33 liter but not exceeding 1 liter.....	gross			
	30	Of a capacity exceeding 0.15 liter but not exceeding 0.33 liter.....	gross			
	40	Of a capacity not exceeding 0.15 liter.....	gross			

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Heading/ Subheading	Stat. Suf- fix	Article Description	Unit of Quantity	Rates of Duty	
				1 General	2 Special
7016		Paving blocks, slabs, bricks, squares, tiles and other articles of pressed or molded glass, whether or not wired, of a kind used for building or construction purposes; glass cubes and other glass smallwares, whether or not on a backing, for mosaics or similar decorative purposes; leaded glass windows and the like; multicellular or foam glass in blocks, panels, plates, shells or similar forms:			
7016.10.00	00	Glass cubes and other glass smallwares, whether or not on a backing, for mosaics or similar decorative purposes ^{3/}	No.....	2.7% ^{1/}	Free (A*, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 60%
7016.90		Other:			
7016.90.10		Paving blocks, slabs, bricks, squares, tiles and other articles of pressed or molded glass.....		8% ^{1/}	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 60%
	10	Bricks and blocks.....	No.		
	50	Other.....	No.		
7016.90.50	00	Other.....	No.....	5% ^{1/}	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 60%
7017		Laboratory, hygienic or pharmaceutical glassware, whether or not graduated or calibrated:			
7017.10		Of fused quartz or other fused silica:			
7017.10.30	00	Quartz reactor tubes and holders designed for insertion into diffusion and oxidation furnaces for production of semiconductor wafers.....	kg.....	Free ^{1/}	50%
7017.10.60	00	Other.....	kg.....	4.6% ^{1/}	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 50%
7017.20.00	00	Of other glass having a linear coefficient of expansion not exceeding 5×10^{-6} per Kelvin within a temperature range of 0°C to 300°C.....	kg.....	6.7% ^{1/}	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 85%
7017.90		Other:			
7017.90.10	00	Microscope slides and micro cover glasses.....	kg.....	Free ^{1/}	85%
7017.90.50	00	Other.....	kg.....	6.7% ^{1/}	Free (A, AU, BH, CL, CO, D, E, IL, JO, KR, MA, OM, P, PA, PE, S, SG) 85%

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Endnotes--page 70 - 42

1/ See 9903.88.03.

2/ See 9903.88.02.

3/ See 9903.88.69.

4/ See 9903.90.08.

5/ See 9903.88.15.

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CHAPTER 90

OPTICAL, PHOTOGRAPHIC, CINEMATOGRAPHIC, MEASURING, CHECKING, PRECISION, MEDICAL OR SURGICAL INSTRUMENTS AND APPARATUS; PARTS AND ACCESSORIES THEREOF

XVIII
90-1

Notes

1. This chapter does not cover:

- (a) Articles of a kind used in machines, appliances or for other technical uses, of vulcanized rubber other than hard rubber (heading 4016), of leather or of composition leather (heading 4205) or of textile material (heading 5911);
 - (b) Supporting belts or other support articles of textile material, whose intended effect on the organ to be supported or held derives solely from their elasticity (for example, maternity belts, thoracic support bandages, abdominal support bandages, supports for joints or muscles) (section XI);
 - (c) Refractory goods of heading 6903; ceramic wares for laboratory, chemical or other technical uses, of heading 6909;
 - (d) Glass mirrors, not optically worked, of heading 7009, or mirrors of base metal or of precious metal, not being optical elements (heading 8306 or chapter 71);
 - (e) Goods of heading 7007, 7008, 7011, 7014, 7015 or 7017;
 - (f) Parts of general use, as defined in note 2 to Section XV, of base metal (Section XV) or similar goods of plastics (chapter 39); however, articles specially designed for use exclusively in implants in medical, surgical, dental or veterinary sciences are to be classified in heading 9021;
 - (g) Pumps incorporating measuring devices, of heading 8413; weight-operated counting or checking machinery, or separately entered weights for balances (heading 8423); lifting or handling machinery (headings 8425 to 8428); paper or paperboard cutting machines of all kinds (heading 8441); fittings for adjusting work or tools on machine tools or water-jet cutting machines, of heading 8466, including fittings with optical devices for reading the scale (for example, "optical" dividing heads) but not those which are in themselves essentially optical instruments (for example, alignment telescopes); calculating machines (heading 8470); valves or other appliances of heading 8481, machines and apparatus (including apparatus for the projection or drawing of circuit patterns on sensitized semiconductor materials) of heading 8486;
 - (h) Searchlights or spotlights of a kind used for cycles or motor vehicles (heading 8512); portable electric lamps of heading 8513; cinematographic sound recording, reproducing or re-recording apparatus (heading 8519); sound-heads (heading 8522); television cameras, digital cameras and video camera recorders (heading 8525); radar apparatus, radio navigational aid apparatus and radio remote control apparatus (heading 8526); connectors for optical fibers, optical fiber bundles and cables (heading 8536); numerical control apparatus (heading 8537); sealed beam lamp units of heading 8539; optical fiber cables of heading 8544;
 - (ij) Searchlights or spotlights of heading 9405;
 - (k) Articles of chapter 95;
 - (l) Monopods, bipods, tripods and similar articles, of heading 9620;
 - (m) Capacity measures, which are to be classified according to their constituent material; or
 - (n) Spools, reels or similar supports (which are to be classified according to their constituent material, for example, in heading 3923 or section XV).
2. Subject to note 1 above, parts and accessories for machines, apparatus, instruments or articles of this chapter are to be classified according to the following rules:
- (a) Parts and accessories which are goods included in any of the headings of this chapter or of chapter 84, 85 or 91 (other than heading 8487, 8548 or 9033) are in all cases to be classified in their respective headings;
 - (b) Other parts and accessories, if suitable for use solely or principally with a particular kind of machine, instrument or apparatus, or with a number of machines, instruments or apparatus of the same heading (including a machine, instrument or apparatus of heading 9010, 9013 or 9031) are to be classified with the machines, instruments or apparatus of that kind;
 - (c) All other parts and accessories are to be classified in heading 9033.

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Notes (con.)

3. The provisions of notes 3 and 4 to section XVI apply also to this chapter.
4. Heading 9005 does not apply to telescopic sights for fitting to arms, periscopic telescopes for fitting to submarines or tanks, or to telescopes for machines, appliances, instruments or apparatus of this chapter or section XVI; such telescopic sights and telescopes are to be classified in heading 9013.
5. Measuring or checking optical instruments, appliances or machines which, but for this note, could be classified both in heading 9013 and in heading 9031 are to be classified in heading 9031.
6. For the purposes of heading 9021, the expression "orthopedic appliances" means appliances for:
 - (a) Preventing or correcting bodily deformities; or
 - (b) Supporting or holding parts of the body following an illness, operation or injury.

Orthopedic appliances include footwear and special insoles designed to correct orthopedic conditions, provided that they are either (1) made to measure or (2) mass-produced, entered singly and not in pairs and designed to fit either foot equally.

7. Heading 9032 applies only to:

- (a) Instruments and apparatus for automatically controlling the flow, level, pressure or other variables of liquids or gases, or for automatically controlling temperature, whether or not their operation depends on an electrical phenomenon which varies according to the factor to be automatically controlled, which are designed to bring this factor to, and maintain it at, a desired value, stabilized against disturbances, by constantly or periodically measuring its actual value; and
- (b) Automatic regulators of electrical quantities, and instruments or apparatus for automatically controlling non-electrical quantities the operation of which depends on an electrical phenomenon varying according to the factor to be controlled, which are designed to bring this factor to, and maintain it at, a desired value, stabilized against disturbances, by constantly or periodically measuring its actual value.

Additional U.S. Notes

1. For the purposes of headings 9001 and 9002, the term "optically worked" refers to glass the surface of which has been ground or polished in order to produce the required optical properties.
2. For the purposes of this chapter, the term "electrical" when used in reference to instruments, appliances, apparatus and machines, refers to those articles the operation of which depends on an electrical phenomenon which varies according to the factor to be ascertained.
3. For the purposes of this chapter, the terms "optical appliances" and "optical instruments" refer only to those appliances and instruments which incorporate one or more optical elements, but do not include any appliances or instruments in which the incorporated optical element or elements are solely for viewing a scale or for some other subsidiary purpose.
4. For the purposes of this chapter, the term "printed circuit assembly" means goods consisting of one or more printed circuits of heading 8534 with one or more active elements assembled thereon, with or without passive elements. For the purposes of this note, "active elements" means diodes, transistors and similar semiconductor devices, whether or not photosensitive, of heading 8541, and integrated circuits of heading 8542.

Statistical Notes

1. For statistical reporting purposes under subheading 9001.10, the unit of quantity "fiber m", as it pertains to optical fiber bundles and cables, is determined by multiplying the number of individual fibers contained therein by the length in meters.
2. For the purposes of statistical reporting number 9025.19.8010, "clinical infrared thermometers" are devices designed to be used to check the body temperatures of humans and animals.

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Heading/ Subheading	Stat. Suf- fix	Article Description	Unit of Quantity	Rates of Duty	
				1 General	2 Special
9018		Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments; parts and accessories thereof: Electro-diagnostic apparatus (including apparatus for functional exploratory examination or for checking physiological parameters); parts and accessories thereof: Electrocardiographs, and parts and accessories thereof: Electrocardiographs.....	No.....	Free ^{5/}	35%
9018.11		Printed circuit assemblies.....	No.....	Free ^{5/}	35%
9018.11.30	00	Other ^{6/}	No.....	Free ^{5/}	35%
9018.12.00	00	Ultrasonic scanning apparatus ^{6/}	No.....	Free ^{5/}	35%
9018.13.00	00	Magnetic resonance imaging apparatus.....	No.....	Free ^{5/}	35%
9018.14.00	00	Scintigraphic apparatus.....	No.....	Free ^{5/}	35%
9018.19		Other: Apparatus for functional exploratory examination, and parts and accessories thereof.....	No.....	Free ^{5/}	55%
9018.19.40	00	Other: Patient monitoring systems.....	No.....	Free ^{5/}	35%
9018.19.75	00	Printed circuit assemblies for parameter acquisition modules.....	No.....	Free ^{5/}	35%
9018.19.95		Other.....	Free ^{5/}	35%
	30	Basal metabolism and blood pressure apparatus ^{6/}	No.		
	35	Electroencephalographs (EEG) and electromyographs (EMG).....	No.		
	50	Other apparatus ^{6/}	No.		
	60	Parts and accessories ^{6/}	No.		
9018.20.00		Ultraviolet or infrared ray apparatus, and parts and accessories thereof.....	Free ^{5/}	35%
	40	Therapeutic.....	No.		
	80	Other.....	No.		
9018.31.00		Syringes, needles, catheters, cannulae and the like; parts and accessories thereof: Syringes, with or without needles; parts and accessories thereof.....	Free ^{11/}	60%
	40	Syringes, with or without their needles: Hypodermic.....	No.		
	80	Other ^{12/}	No.		
	90	Parts and accessories.....	No.		
9018.32.00	00	Tubular metal needles and needles for sutures and parts and accessories thereof.....	No.....	Free ^{11/}	55%
9018.39.00		Other.....	Free	30%
	20	Bougies, catheters, drains and sondes, and parts and accessories thereof: Rubber catheters.....	doz.		
	40	Other.....	No.		
	50	Other.....	No.		

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Endnotes--page 90 - 38

- 1/ See 9903.88.02.
- 2/ See 9903.88.15.
- 3/ See 9903.88.03.
- 4/ See 9903.90.08.
- 5/ See 9903.88.01.
- 6/ See 9903.88.69.
- 7/ See 9903.88.15, 9903.88.25, 9903.88.26, 9903.88.27 and 9903.88.28.
- 8/ See 9903.88.03 and U.S. note 19 to subchapter III, chapter 99.
- 9/ See General Note 6.
- 10/ See 9903.88.03, 9903.88.21, 9903.88.22, 9903.88.23 and 9903.88.24.
- 11/ See 9903.91.03.
- 12/ See 9903.91.10.
- 13/ See 9817.84.01 and 9903.88.01.
- 14/ See 9903.88.01 and U.S. note 19 to subchapter III, chapter 99.

ATTACHMENT 4

PHARMACEUTICAL TECHNOLOGIES

Merck and Pfizer Collaborate with Corning to Modernize Pharmaceutical Glass Packaging

CORNING, N.Y. | Corning Incorporated | July 20, 2017

Collaborations result in development of Corning Valor™ Glass; drive significant U.S. investment and job creation

The White House Office of American Innovation facilitates cross-industry technology collaboration and U.S. investment

Merck (NYSE: MRK), Pfizer (NYSE: PFE) and Corning Incorporated (NYSE: GLW) today announced collaborations that have enabled the modernization of pharmaceutical packaging with the introduction of Corning Valor™ Glass. This revolutionary pharmaceutical glass packaging solution enhances the storage and delivery of today's drug formulations and provides more reliable access to medicines essential to public health.

Deep pharmaceutical formulation and manufacturing process insights from Merck and Pfizer, in combination with Corning's glass science and precision forming capabilities helped deliver an exceptional glass packaging solution for injectable drugs in vials and cartridges. The companies' continued collaborations will focus on additional evaluations and the deployment of this new innovation.

Corning Valor Glass packaging offers superior chemical durability, strength and damage resistance. These qualities enable increased throughput and more reliable access to state-of-the-art medicines for patients, while maintaining a high level of quality assurance for pharmaceutical companies.

The White House Office of American Innovation has encouraged this initiative as a model of cross-industry technology collaboration and economic investment. President Donald J. Trump said, "My administration is committed to streamlining the regulatory process so that it's easier for companies to invest and innovate here in America. Today, I'm pleased to recognize Merck, Pfizer, and Corning for collaborating to modernize pharmaceutical glass packaging with Valor Glass and bring important manufacturing jobs to the United States."

As a result of Merck and Pfizer's commitment to improving glass quality and promising results from their initial testing, Corning is making an initial investment of \$500 million and creating 1,000 new U.S. jobs as the first part of a planned investment of \$4 billion and 4,000 new high-tech jobs.

Kenneth C. Frazier, Merck's chairman and chief executive officer, said, "Merck is proud to have participated from its inception in the development of Valor Glass with Corning. Biologics today are on the leading edge of scientific innovation, and Valor Glass represents a similar advancement in materials science: glass that is purpose-built for medicines and vaccines. Merck plans to convert several injectable products to this exceptional new glass packaging solution, pending appropriate regulatory approvals."

"We joined forces with Corning to advance this revolutionary new glass for medicines that are critical to patients. Our initial trial results with Valor Glass show promise, and we are working with Corning to assess the full potential of this glass solution on products at several of our manufacturing sites," Ian C. Read, Pfizer's chairman and chief executive officer, said.

Wendell P. Weeks, Corning Incorporated's chairman, chief executive officer, and president said, "Making this next-generation product requires a new, advanced manufacturing platform, and we plan to build that platform right here in the United States. All of this is made possible by our great customers like Merck and Pfizer and the strong support of the Administration, the Office of American Innovation,

and the FDA's Emerging Technology Team. We believe this is great news for patients, for the industry, and for the economy."

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

About Corning Incorporated

Corning (www.corning.com) is one of the world's leading innovators in materials science, with a 166-year track record of life-changing inventions. Corning applies its unparalleled expertise in glass science, ceramics science, and optical physics along with its deep manufacturing and engineering capabilities to develop category-defining products that transform industries and enhance people's lives. Corning succeeds through sustained investment in RD&E, a unique combination of material and process innovation, and deep, trust-based relationships with customers who are global leaders in their industries.

Corning's capabilities are versatile and synergistic, which allows the company to evolve to meet changing market needs, while also helping our customers capture new opportunities in dynamic industries. Today, Corning's markets include optical communications, mobile consumer electronics, display technology, automotive, and life sciences vessels. Corning's industry-leading products include damage-resistant cover glass for mobile devices; precision glass for advanced displays; optical fiber, wireless technologies, and connectivity solutions for state-of-the-art communications networks; trusted products to accelerate drug discovery and delivery; and clean-air technologies for cars and trucks.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2016 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

PFIZER DISCLOSURE NOTICE: The information contained in this release is as of July 20, 2017. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about collaborations with respect to pharmaceutical packaging, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development; uncertainties regarding the commercial success of and the ability to realize the anticipated benefits of the collaborations; whether and when regulatory approvals may be received for any new packaging solutions; other business effects, including the effects of industry, market, economic, political or regulatory conditions; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 10-Q and Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

Corning Incorporated - Forward-Looking and Cautionary Statements

This press release contains "forward-looking statements" (within the meaning of the Private Securities Litigation Reform Act of 1995), which are based on current expectations and assumptions about Corning's financial results and business operations, that involve substantial risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include: the effect of global political, economic and business conditions; conditions in the financial and credit markets; currency fluctuations; tax rates; product demand and industry capacity; competition; reliance on a concentrated customer base; manufacturing efficiencies; cost reductions; availability of critical components and materials; new product commercialization; pricing fluctuations and changes in the mix of sales between premium and non-premium products; new plant start-up or restructuring costs; possible disruption in commercial activities due to terrorist activity, armed conflict, political or financial instability, natural disasters, adverse weather conditions, or major health concerns; adequacy of insurance; equity company activities; acquisition and divestiture activities; the level of excess or obsolete inventory; the rate of technology change; the ability to enforce patents; product and components performance issues; retention of key personnel; stock price fluctuations; and adverse litigation or regulatory developments. These and other risk factors are detailed in Corning's filings with the Securities and Exchange Commission. Forward-looking statements speak only as of the day that they are made, and Corning undertakes no obligation to update them in light of new information or future events.

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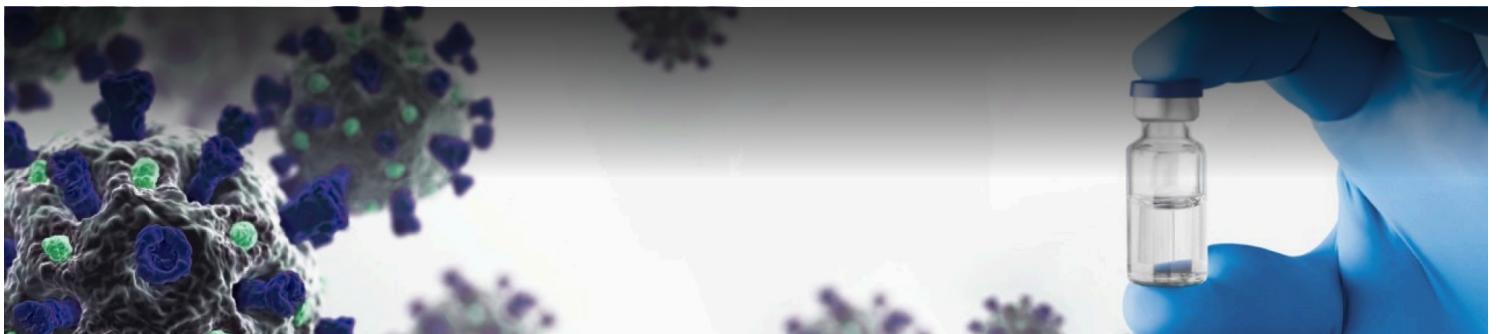
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ATTACHMENT 5



U.S. Departments of Defense, Health & Human Services select Corning Valor® Glass packaging to accelerate delivery of COVID-19 vaccines

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PHARMACEUTICAL TECHNOLOGIES

Corning Valor® Glass Selected to Help Accelerate Delivery of COVID-19 Vaccines and Drugs

CORNING, N.Y. | Corning Incorporated | June 09, 2020

Corning to receive \$204M in funding to substantially expand domestic manufacturing capacity under White House's Operation Warp Speed Initiative

Corning Incorporated (NYSE: GLW) today announced it will receive \$204 million from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services through its partnership with the Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense and Army Contracting Command. Under the agreement, Corning will substantially expand its domestic manufacturing capacity of Corning Valor® Glass vials to support the vaccination and treatment of billions of patients. Corning will provide priority access to designated BARDA vaccine and drug development partners.

Wendell P. Weeks, Corning's chairman and chief executive officer, said, "We're delighted that BARDA has selected Corning as a packaging provider for COVID-19 vaccines and treatments. Our Valor Glass provides the strongest, fastest to fill, and highest-quality pharmaceutical glass vials ever produced. It helps protect patients and addresses existing bottlenecks. Corning is ready to do our part in the fight against the pandemic, as well as to help prepare for future public health emergencies."

At the White House in 2017, Corning joined Merck and Pfizer to announce a Valor Glass collaboration focused on modernizing pharmaceutical glass packaging. Through investment in Valor Glass manufacturing capacity under Operation Warp Speed (OWS), the U.S. government will strengthen the U.S. pharmaceutical supply chain by directly addressing existing constraints and shortages.

"Valor Glass sets a new standard for quality and performance in pharmaceutical packaging. It is purpose-built for pharmaceuticals and is uniquely positioned to enable faster, more reliable drug manufacture and delivery – attributes that are critical to the SARS-CoV-2 pandemic response," said Brendan Mosher, vice president and general manager, Corning Pharmaceutical Technologies.

Valor Glass offers superior chemical durability and minimizes particulate contamination, enhancing product quality. The specialized glass allows for faster filling and capping, increasing manufacturing throughput by as much as 50% on conventional filling lines, and reduces the time needed to manufacture vaccines and therapies. Up to ten times stronger than conventional borosilicate glass, Valor Glass reduces damage and breakage during manufacturing and shipping, helping to ensure more treatments reach patients. This revolutionary glass is advantaged for highly specialized formulations that may be utilized in next-generation therapies due to manufacturing quality standards that are more stringent than those used for conventional vials.

This critical investment from BARDA will enable Corning to accelerate the scale up of Valor Glass' tubing and vial manufacturing assets at three U.S. facilities in Big Flats, New York; Durham, North Carolina; and Vineland, New Jersey. The increase in vial manufacturing surge capacity will help meet the rapidly growing demand for glass containers as pharmaceutical companies enter COVID-19 clinical trials towards eventual approval of vaccines and treatments.

Caution Concerning Forward-Looking Statements

This press release contains "forward-looking statements" (within the meaning of the Private Securities Litigation Reform Act of 1995), which are based on current expectations and assumptions about Corning's financial results and business operations, that involve substantial risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include: the duration and severity of the recent COVID-19 (coronavirus) outbreak, and its ultimate impact across our businesses on demand, operations and our global supply chains; the effects of acquisitions, dispositions and other similar transactions by the Company, the effect of global business, financial, economic and political conditions; tariffs and import duties; currency fluctuations between the U.S. dollar and other currencies, primarily the Japanese yen, New Taiwan dollar, euro, Chinese yuan, and South Korean won; product demand and industry capacity; competitive products and pricing; availability and costs of critical components and materials; new product development and commercialization; order activity and demand from major customers; the amount and timing of our cash flows and earnings and other conditions, which may affect our ability to pay our quarterly dividend at the planned level or to repurchase shares at planned levels; possible disruption in commercial activities due to terrorist activity, cyber-attack, armed conflict, political or financial instability, natural disasters, or major health concerns; unanticipated disruption to equipment, facilities, IT systems or operations; effect of regulatory and legal developments; ability to pace capital spending to anticipated levels of customer demand; rate of technology change; ability to enforce patents and protect intellectual property and trade secrets; adverse litigation; product and components performance issues; retention of key personnel; customer ability, most notably in the Display Technologies segment, to maintain profitable operations and obtain financing to fund their ongoing operations and manufacturing expansions and pay their receivables when due; loss of significant customers; changes in tax laws and regulations including the Tax Cuts and Jobs Act of 2017; and the potential impact of legislation, government regulations, and other government action and investigations.

For a complete listing of risks and other factors, please reference the risk factors and forward-looking statements described in our annual reports on Form 10-K and quarterly reports on Form 10-Q. Forward-looking statements speak only as of the day that they are made, and Corning undertakes no obligation to update them in light of new information or future events.

Web Disclosure

In accordance with guidance provided by the SEC regarding the use of company websites and social media channels to disclose material information, Corning Incorporated ("Corning") wishes to notify investors, media, and other interested parties that it uses its website (<http://www.corning.com/worldwide/en/about-us/news-events.html>) to publish important information about the company, including information that may be deemed material to investors, or supplemental to information contained in this or other press releases. The list of websites and social media channels that the company uses may be updated on Corning's media and website from time to time. Corning encourages investors, media, and other interested parties to review the information Corning may publish through its website and social media channels as described above, in addition to the company's SEC filings, press releases, conference calls, and webcasts.

About Corning Incorporated

Corning (www.corning.com) is one of the world's leading innovators in materials science, with a 169-year track record of life-changing inventions. Corning applies its unparalleled expertise in glass science, ceramic science, and optical physics along with its deep manufacturing and engineering capabilities to develop category-defining products that transform industries and enhance people's lives. Corning succeeds through sustained investment in RD&E, a unique combination of material and process innovation, and deep, trust-based relationships with customers who are global leaders in their industries. Corning's capabilities are versatile and synergistic, which allows the company to evolve to meet changing market needs, while also helping our customers capture new opportunities in dynamic industries. Today, Corning's markets include mobile consumer electronics, optical communications, automotive technologies, life sciences technologies, and display technologies.

Operation Warp Speed

Operation Warp Speed is a U.S. government-sponsored public-private partnership to facilitate, at an unprecedented pace, the development, manufacturing, and distribution of COVID-19 countermeasures, between components of HHS, including the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH), and BARDA; the Department of Defense; private firms; and other federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs. Operational Warp Speed coordinates existing HHS-wide efforts, including the NIH's ACTIV partnership for vaccine and therapeutic development, NIH's RADx initiative for diagnostic development, and work by BARDA.

About HHS, ASPR, and BARDA:

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. To date, 55 BARDA-supported products have achieved regulatory approval, licensure or clearance. To learn more about federal support for the nationwide COVID-19 response, visit coronavirus.gov.

About the JPEO-CBRND:

The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) is the DoD Joint Service's lead for development, acquisition, fielding and life-cycle support of chemical, biological, radiological, and nuclear defense equipment and medical countermeasures. As an effective acquisition program, the JPEO-CBRND puts capable and supportable systems in the hands of the service members and first responders, when and where it is needed, at an affordable price. Our vision is a resilient Joint Force, enabled to fight and win unencumbered by a chemical, biological, radiological, or nuclear environment, championed by innovative and state-of-the-art solutions.

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ATTACHMENT 6



Corning Receives Nearly \$104 Million in Additional Funding from BARDA for Planned Domestic Glass Tubing and Vial Manufacturing

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PHARMACEUTICAL TECHNOLOGIES

Corning Receives Nearly \$104 Million in Additional Funding from BARDA for Planned Domestic Glass Tubing and Vial Manufacturing

CORNING, N.Y. | Corning Incorporated | September 15, 2022

Corning Incorporated (NYSE: GLW) today announced it will receive \$103.8 million in additional funding from the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) in partnership with the Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense and Army Contracting Command (JPEO-CBRND). The funding will support Corning's planned manufacturing expansion of advanced, high-quality pharmaceutical glass tubing and vials, helping the health care industry rapidly scale manufacturing to address current and future public health challenges.

"Corning's pharmaceutical glass packaging has played a critical role in ensuring the safe and on-time delivery of critical medications," said Brendan Mosher, vice president and general manager, Corning Pharmaceutical Technologies. "Our Valor® Glass and Velocity® Vials are some of the strongest, fastest to fill, and highest-quality pharmaceutical glass vials available. Our products play a critical role in helping to protect patients by improving glass quality, lowering the risk of contamination, and helping to accelerate the delivery of lifesaving treatments."

Through this planned investment in Corning's pharmaceutical glass manufacturing capacity, the U.S. government will strengthen the domestic pharmaceutical supply chain by directly addressing manufacturing efficiency constraints. Under the new agreement funded by BARDA, Corning will continue to expand pharmaceutical tubing manufacturing capacity in Vineland, New Jersey, and vial manufacturing capacity in Durham, North Carolina.

Caution Concerning Forward-Looking Statements

The statements contained in this release that are not historical facts or information and contain words such as "will," "believe," "anticipate," "expect," "intend," "plan," "seek," "see," "would," and "target" and similar expressions are forward-looking statements. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include estimates and assumptions related to economic, competitive and legislative developments. Such statements relate to future events that by their nature address matters that are, to different degrees, uncertain. These estimates are subject to change and

uncertainty which are, in many instances, beyond our control. There can be no assurance that future developments will be in accordance with management's expectations. Actual results could differ materially from those expected by us, depending on the outcome of various factors. We do not undertake to update forward-looking statements.

Although the Company believes that these forward-looking statements are based upon reasonable assumptions regarding, among other things, current estimates and forecasts, general economic conditions, its knowledge of its business, and key performance indicators that impact the Company, actual results could differ materially. Some of the risks, uncertainties and other factors that could cause actual results to differ materially from those expressed in or implied by the forward-looking statements include, but are not limited to: the duration and severity of the COVID-19 pandemic, and its impact across our businesses on demand, personnel, operations, our global supply chains and stock price; global economic trends, competition and geopolitical risks, or an escalation of sanctions, tariffs or other trade tensions, and related impacts on our businesses' global supply chains and strategies; changes in macroeconomic and market conditions, market volatility, interest rates, capital markets, the value of securities and other financial assets, precious metals, oil, natural gas and other commodities and exchange rates (particularly between the U.S. dollar and the Japanese yen, new Taiwan dollar, euro, Chinese yuan and South Korean won), consumer demand, and the impact of such changes and volatility on our financial position and businesses; product demand and industry capacity; competitive products and pricing; availability and costs of critical components, materials, equipment, natural resources and utilities; new product development and commercialization; order activity and demand from major customers; the amount and timing of our cash flows and earnings and other conditions, which may affect our ability to pay our quarterly dividend at the planned level or to repurchase shares at planned levels; disruption to Corning's, our suppliers' and manufacturers' supply chain, logistics, equipment, facilities, IT systems, operations or commercial activities due to terrorist activity, cyber-attack, armed conflict, political or financial instability, natural disasters, international trade disputes or major health concerns; loss of intellectual property due to theft, cyber-attack, or disruption to our information technology infrastructure; effects of acquisitions, dispositions and other similar transactions; effect of regulatory and legal developments; ability to pace capital spending to anticipated levels of customer demand; our ability to increase margins through implementation of operational changes, pricing actions and cost reduction measures without impacting revenues; rate of technology change; ability to enforce patents and protect intellectual property and trade secrets; adverse litigation; product and components performance issues; attraction and retention of key personnel; customer ability to maintain profitable operations and obtain financing to fund ongoing operations and manufacturing expansions and pay receivables when due; loss of significant customers; changes in tax laws, regulations and international tax standards; the impacts of audits by taxing authorities; the potential impact of legislation, government regulations, and other government action and investigations; and other risks detailed in Corning's SEC filings.

For a complete listing of risks and other factors, please reference the risk factors and forward-looking statements described in our annual reports on Form 10-K and quarterly reports on Form 10-Q.

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In accordance with guidance provided by the SEC regarding the use of company websites and social media channels to disclose material information, Corning Incorporated ("Corning") wishes to notify investors, media, and other interested parties that it uses its website (<https://www.corning.com/worldwide/en/about-us/news-events.html>) to publish important information about the company, including information that may be deemed material to investors, or supplemental to information contained in this or other press releases. The list of websites and social media channels that the company uses may be updated on Corning's media and website from time to time. Corning encourages investors, media, and other interested parties to review the information Corning may publish through its website and social media channels as described above, in addition to the company's SEC filings, press releases, conference calls, and webcasts.

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