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May 7, 2025

Section 232 Investigation Team
Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce

RE: Comment to XRIN 0694-XC120 Pharmaceuticals Section 232 Investigation

To Whom It May Concern:

As President and CEO of Colorcon, Inc. I submit the comments below for your review and consideration in the above referenced investigation.

Colorcon is a multinational corporation established in 1961 and is headquartered in Harleysville, Pennsylvania. Our best-in-class products and technologies are complemented by our pharma industry focus and value-added services to support branded, generic and over-the- counter medicines, and nutraceutical product development from concept to commercialization. We actively supply over 4,000 pharmaceutical manufacturers worldwide with over 700 located in the United States, and we manufacture over 16,000 individual products.

Our consultative service model assists our customers in the development, manufacturing process scale up and regulatory approval of medicines primarily in the form of tablets and capsules. We achieve commercial success through the ongoing supply of specialized, high quality, pharmaceutical ingredients and packaging materials that our customers use in the manufacture of the medication. These specialized ingredients are designed to meet the requirements of the medication and achieve functions such as delayed or controlled drug release, improved stability, optimized taste and enhanced appearance. These technologies bring benefits of distinctive product identification, safety, brand identity, extended shelf-life and increased consumer appeal.

Our trusted partner reputation is built around the strategic concepts of local service and support, a robust and secure supply chain and establishing capacity to supply in advance of demand. We are committed to being a key supplier throughout the lifecycle of the medicine and, as a result, our footprint is comprised of 19 manufacturing facilities, 26 technical service laboratories and more than 2,100 employees globally.

While we are a global enterprise, we maintain a significant footprint within the United States. In addition to our global headquarters, which hosts our global strategic functions, and our information technology hub and innovation center, we also maintain 5 manufacturing facilities, 2 technical service laboratories and more than 650 employees in the United States.

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Our flagship product is a range of fully formulated pharmaceutical film coating systems widely known under the Opadry® brand name. These systems are custom designed and manufactured as a combination of ingredients that are used in the manufacturing of film coated medicines. The Opadry® family of products are manufactured close to our customers and supplied on a just-in-time supply basis across a network of 9 manufacturing locations worldwide, including a state-of-the-art location in West Point, Pennsylvania.

Products exclusively manufactured in the United States include (i) Starch 1500® and Starcap 1500® pharmaceutical grade starches; (ii) Surelease®, a sustained release aqueous coating system; (iii) HT® synthetic colors, Phthalavin™ delayed release polymer; and (iv) No-Tox® specialized pharmaceutical printing inks.

[redacted]

Our strategy is to qualify multiple sources of key raw materials to mitigate supply risk, achieve pharmaceutical quality requirements and optimize cost. This is balanced against a goal to localize the supply, and in doing so simplifying supply logistics, reducing transportation costs and increasing the agility of our operations. Despite our focus on sourcing locally, it has not been possible for Colorcon to fulfill all its sourcing needs for its US production with raw materials produced in the United States. For example, Colorcon must import the following raw materials: anatase titanium dioxide, carmine, iron oxide, talc, hydroxypropyl methyl cellulose (HPMC), [redacted] riboflavin, and silica gel. Of these materials, anatase titanium dioxide, carmine, iron oxide, and talc are not currently produced in the United States. The others, HPMC, [redacted], riboflavin and silica gel, are not currently available in the United States in the grade and volumes required or would be prohibitively expensive to use. More detailed information about these imported raw materials, including harmonized tariff codes, is set forth below.

Anatase titanium dioxide (2823.00.00)

Colorcon purchases pharmaceutical grade anatase titanium dioxide (Anatase TiO2) produced using a chemical manufacturing process resulting in a high purity, high whiteness material and a high level of opacity. This anatase grade of titanium dioxide is not produced in the United States because of the unavailability of the ilmenite ore used as a starting material, and also because of the complexity of the chemical process used to refine it. Ilmenite ore is located in China, Canada, Norway, Australia, South Africa, Vietnam, Madagascar and India.

Carmine (3203.00.00)

Carmine is used as a natural red pigment in pharmaceuticals and is only commercially produced in Peru from the dye extracted from cochineal insects. Once harvested, the insects are processed to extract carminic acid, which is then filtered, precipitated, washed, and dried to produce carmine powder. The life

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cycle of the cochineal insects is highly dependent on the growing conditions in South America and has not yet been replicated elsewhere. Please note the demand for carmine is expected to increase as the natural based colors have increased consumer appeal.

Iron oxide (2821.10.00)

High purity iron oxide for use in pharmaceutical products is manufactured by several suppliers with high purity production sites in Italy, China, India and Germany. Each site produces iron oxide with specific particle morphology that affects the color, shade and the way the color develops during use and at this time these grades are not interchangeable in the Colorcon application and there are no United States based options.

Talc (2526.20.00)

High-purity, asbestos-free talc ore is mined and processed to manufacture pharmaceutical grade talc. The whiteness and purity of the finished talc is based on the talc ore used. Talc from many sources includes impurities which prevent its use in Colorcon's application. Colorcon has been unable to identify a supplier that extracts and processes pharmaceutical grade talc in the United States.

HPMC (3912.39.00)

Colorcon is aware that United States based suppliers of HPMC have capacity constraints and are unable to produce the volume of HPMC needed in the grade required to produce pharmaceutical excipients. Major investment in construction of new facilities and manufacturing equipment will be necessary to expand United States based suppliers' capacity to produce the grade of HPMC required by Colorcon.

[redacted]

Riboflavin (2936.23.00)

Pharmaceutical grade riboflavin is produced by manufacturers in China, the EU, Switzerland and India but not currently in the United States. The manufacturing process employs special vessels for fermentation, utilizing genetically modified microorganisms and a biomass medium. Once fermented, the

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riboflavin is separated from the biomass and purified by dissolving in acid, filtering and spray drying to make the final product. In Colorcon's applications, the specific color shade of the riboflavin produced must conform to specifications. The shade of riboflavin may vary depending on the manufacturer. We expect that a supplier would need approximately 5 years to construct and qualify a site for pharmaceutical grade product in the US.

Silica gel (2811.22.10)

Silica gel is produced in China, India, Japan and the United States. Colorcon is unable to use the silica gel produced by United States suppliers because it is unable to meet our physical specifications. To date, the United States suppliers have not been willing to change their process to meet Colorcon requirements. We believe US suppliers may need 3 -5 years to update their process to meet our required specifications.

As described above, anatase titanium dioxide, carmine, iron oxide, and talc cannot currently be produced in the United States. Imposing tariffs on the import of these raw materials is unlikely to promote domestic production – it will likely increase manufacturing costs for purchasers of those materials. An exemption from tariffs should be considered for these raw materials so that they can continue to support our manufacturing supply chain.

While HPMC, [ ], riboflavin and silica gel could potentially be produced in the United States to meet Colorcon's requirements for use in pharmaceutical products, it will take substantial investment by the manufacturers of such raw materials to achieve this as well as time. Once such grades and volumes are available from United States based suppliers, it would potentially take 18 months to qualify them for use in Colorcon applications.

We would suggest a consideration for delayed application of tariffs to HPMC, [ ], riboflavin and silica gel because it will take several years and considerable investment for domestic production of these raw materials. Additionally, incentives to stimulate United States based production of these raw materials should be considered to encourage domestic production.

Responses to Section 232 Notice Questions

Below are the Colorcon responses to the best of our ability in the areas of interest stated in the Section 232 Notice Letter. We have limited our answers to the pharma ingredients topics which are the areas of our involvement. In addition, we have excluded answers to points (v, vi, vii, ix, x) since we do not have information pertaining to those areas.

(i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;

[redacted]

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[redacted]

(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand.

Colorcon is a United States headquartered domestic producer of a full range of key pharmaceutical ingredients for tablets and capsules. Our long-standing strategy is to ensure we have extra domestic capacity available to meet medium-term growth expectations. This affords us the available capacity to supply the projected growth in the United States market and we believe also positions us to meet increased domestic demand linked to increased localization of United States based pharmaceutical manufacturing.

(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients.

As outlined earlier in this document, Colorcon accesses several foreign raw material suppliers and they play a meaningful role in supporting the production of high-quality pharmaceutical ingredients. In many cases they have been chosen due to the specialized, technical nature of the material, the high purity and quality necessary for pharmaceutical applications or the availability of precursor materials used in their manufacture.

(iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks;

It is our view that for pharmaceutical ingredients and key raw materials used in their production there is an appropriate diversification of the supplier base. There are a few noteworthy exceptions, examples of which we have outlined earlier in this document. Colorcon works proactively with our suppliers to de-risk the supply chain. It is important to note that for pharmaceuticals approved by the United States Food and Drug Administration (US FDA) significant changes in the suppliers of the pharmaceutical ingredients are subject to a controlled management process. Depending on the level of the change as outlined in the US FDA Scale up and post approval changes (SUPAC) guidelines this may require significant investment in time and cost, which can present risk to the qualification of a new or alternate supplier.

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(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance;

Colorcon is well positioned to meet short-term increases in domestic demand for pharmaceutical ingredients and could install additional capacity over a 24–36-month timeframe. Colorcon would need to continue to source several key specialty raw materials outside of the United States but would work diligently to develop local sources where possible. Localization of raw material supply is a key strategy, but we have found that available suppliers often do not possess the agility to develop grades that meet technical specifications and the quality standards of pharmaceutical ingredients and find it difficult to do so in a cost-effective way. We believe this would take more time and lag the growth in Colorcon's domestic production capacity.

In summary, Colorcon has developed our pharmaceutical ingredients supply capabilities to closely align with the requirements of the global pharmaceutical industry over the last 60 years. Our primary mission is to ensure supply reliability, maintain high-quality standards, and achieve cost efficiency. Consequently, we possess the agility and adaptability required to support United States based pharmaceutical production. We should recognize that several key raw materials will continue to be sourced outside of the United States for the foreseeable future. We do call for consideration of support during this transition in the form of tariff exemptions and/or incentives.

Sincerely,

Simon Tasker
President and CEO
Colorcon, Inc.