UNITED STATES COURT OF INTERNATIONAL TRADE

ACETRIS HEALTH, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Court No. 18-00040**
	)	
UNITED STATES,	)	
	)	
Defendant.	)	
	)	

COMPLAINT

Plaintiff Acetris Health, by its undersigned attorneys, does for its Complaint in this action hereby state and allege as follows:

I. INTRODUCTION

This complaint arises from the January 30, 2018 Final Determination of U.S. Customs and Border Protection ("CBP"), H289700, 83 FR 5118 (Feb. 5, 2018), holding that (1) for purposes of government procurement the prescription drug, Rosuvastatin Calcium Tablets, is not "manufactured in the United States" within the meaning of the term "U.S.-made end products" set forth in the Federal Acquisition Regulation ("FAR") because the separate government procurement provisions of the Trade Agreements Act of 1979 ("the TAA"), 19 U.S.C. 2511-2518, require that a designated country (non-U.S.) end product be "wholly" manufactured in that country, and (2) the country of origin of Rosuvastatin Calcium Tablets is India.

The end product the government is seeking to procure is a prescription drug approved by the U.S. Food & Drug Administration ("FDA"). Under the FAR, the government can purchase U.S.-made end products that include domestic end products preferred under the Buy American

Act ("BAA"), 41 U.S.C. 8301 *et seq.*, and foreign products of designated countries eligible for a waiver of BAA preferences under the TAA if wholly the manufacture of the designated country or, if materials from other countries are used in the manufacture of the product, the last substantial transformation of the product occurs in a designated country. Importantly, under the FAR, a product does not need to be eligible for a TAA waiver if it is a U.S.-made end product. A U.S.-made end product is an end product that is manufactured in the United States, without regard to the country of origin of the components or whether the product is substantially transformed in the United States. A product may also qualify as a U.S.-made end product if it is substantially transformed in the U.S.

Here, Rosuvastatin Calcium Tablets indisputably are manufactured in the U.S. and are thus U.S.-made end products under the FAR. Every manufacturing activity necessary to manufacture this drug from active and inactive ingredients sourced in the United States, India and other countries occurs in the United States. Rosuvastatin Calcium Tablets also are substantially transformed in the U.S. because while the chemical that becomes the active ingredient for Rosuvastatin Calcium Tablets, referred to by the FDA as Bulk Drug Substance, is sourced from India, virtually all of the other ingredients originate elsewhere; 100 percent of the complex formulation and processing necessary to manufacture the FDA-approved Rosuvastatin Calcium Tablets from active and inactive ingredients occurs in the U.S.; and the chemical sourced from India cannot be sold to consumers as a drug. Accordingly, CBP's Final Determination is wrong in finding Rosuvastatin Calcium Tablets are manufactured in India and wrong in finding that the last substantial transformation of Rosuvastatin Calcium Tablets occurred in India.

Manufacture, marketing and distribution of prescription drugs in the U.S. are highly regulated by the FDA. Before a product can be sold in the United States as a prescription drug for medicinal purposes, FDA requires that the product must be demonstrated safe and effective for treatment of a specific human disease or condition and approved by the FDA as such. Rosuvastatin Calcium Tablets may only be sold in the United States to consumers if formulated and manufactured in accordance with the FDA approval authority (either a New Drug Application or an Abbreviated New Drug Application), prescribed by medical professionals, and dispensed by licensed pharmacies. The approval authority required to market a product for use as a drug ("Drug Product") specifies the exact amount of active and inactive ingredients and manufacturing processes required by the FDA for the product to be safe and effective for its intended use. Deviations from the approved formulation and manufacturing processes specified in the Rosuvastatin Calcium Tablets approval authority can result in an adulterated product, for which distribution is unlawful. It is the approval authority that gives the Drug Product manufactured in accordance with that authority its commercial value.

Bulk Drug Substances that are used in the formulation of prescription drugs are not demonstrated safe and effective for treatment of a human disease or condition and are not approved by the FDA for use as prescription drugs. FDA prohibits manufacturers of Bulk Drug Substances from marketing them for use as medicines, and it is a crime to do so. As regulated by the FDA, Bulk Drug Substances are producer products used in manufacturing processes (or for research) only, and have no use or value as consumer products. In short, a raw chemical is not a medicine intended for human consumption and cannot be used as such.

The manufacture of Rosuvastatin Calcium Tablets transforms the Bulk Drug Substance into a new and different product with a different use and involves complex manufacturing processes requiring many hours and expensive equipment. Moreover, the costs and value of Bulk Drug Substance and Drug Product are very different: The cost of manufacturing Rosuvastatin Calcium Tablets is significantly more than the cost of purchasing the Bulk Drug Substance. More importantly, even if the molecular structure of the various ingredients in the approved drug formulation are theoretically identifiable, the market value of the manufactured Drug Product is significantly greater than the value of the Bulk Drug Substance. Because the Bulk Drug Substance has no use as a medicine, the increase in the value of the Rosuvastatin Calcium Tablets – an FDA-approved formulation of multiple active and inactive ingredient – is disproportionate to the incremental added cost of producing the Rosuvastatin Calcium Tablets from Bulk Drug Substance.

For all these reasons, this complaint requests a determination that Rosuvastatin Calcium Tablets are manufactured in the United States and also are substantially transformed in the United States where the raw chemical active and inactive ingredients are utilized in the formulation and manufacture of usable Drug Product with a name, character and use different from each of the underlying active and inactive ingredients.

II. CAUSE OF ACTION

1. This action is commenced to seek de novo judicial review of a Final Determination of CBP, rendered pursuant to Section 305(g)(1) of the Trade Agreements Act of 1979, concerning the country of origin of Rosuvastatin Calcium Tablets manufactured in the United States for Federal government procurement purposes ("the Final

Determination"). Under 28 U.S.C. 2640(a), this Court reaches its decision upon the basis of the record made before the Court. *See also Energizer Battery, Inc. v. United States*, 190 F.Supp.3d 1308 (Ct. Int'l Trade 2016). Notice of the Final Determination was published in the Federal Register on February 5, 2018, (83 Fed. Reg. 5118).

III. JURISDICTION

2. This Court has exclusive subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1581(e).

3. The payment of duties, taxes or fees is not a jurisdictional prerequisite to the commencement of this action.

IV. STANDING

4. Acetris Health, LLC ("Acetris") is a generic pharmaceutical distributor specializing in providing cost effective prescription Drug Products to the U.S. Government, including Rosuvastatin Calcium Tablets which are the subject of the Final Determination to which Acetris was a party-at-interest. Further, Acetris is a distributor in the United States of other generic pharmaceutical products which are "like products" to the goods which are the subject of the challenged Final Determination.

5. Acetris has standing to commence this action pursuant to 28 U.S.C. §2631(e) and, independently, pursuant to 28 U.S.C. §2631(k)(2)(B).

V. STATEMENT OF FACTS AND GENERAL ALLEGATIONS

Acetris' Government Contract and Request for Final Determination

6. Acetris supplies Rosuvastatin Calcium Tablets (the "Drug") as an end product to the U.S. Department of Veterans Affairs ("VA") under a contract committing the VA purchase its entire requirement for the Drug from Acetris in exchange for a very low price. The Drug covered by the contract is approved by the FDA and manufactured for sale in the United States pursuant to Abbreviated New Drug Application ("ANDA") No. 079170. Pursuant to ANDA No. 079170, the Drug is approved for treating adult patients with hypertriglyceridemia as an adjunct to diet, adult patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet, and adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB (collectively "FDA Approved Indications").

7. The Drug is a commercial off the shelf ("COTS") product.

8. That contract contains the Trade Agreement clause at 48 C.F.R. 52.225-5, which permits Acetris to provide the Drug if it is (1) a domestic end product as defined in the Buy America Act ("BAA"), (2) a U.S. manufactured product that is not a domestic end product, (3) a product that is substantially transformed in the U.S. or (4) an eligible product from a foreign country that is a designated country as permitted by the Trade Agreements Act.

9. The first, second and third categories of permitted products are subsumed in the definition of U.S.-made end product, with the third category of product having been permitted under the clause by a regulatory re-write designed to make sure that products substantially transformed in the U.S. (previously not permitted under the clause) were treated equally with products substantially transformed in designated countries. 63 Fed.

Reg. 51642; 64 Fed. Reg. 72414. The fourth category of permitted products is captured in the clause's definition of designated country end products, and is the only portion of the clause derived from the waiver authority under the TAA for certain foreign products that would otherwise be discriminated against under the BAA.

10. Under the FAR, domestic end product means: (1) An unmanufactured end product mined or produced in the United States; (2) An end product manufactured in the United States, if - (i) The cost of its components mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. Components of foreign origin of the same class or kind as those that the agency determines are not mined, produced, or manufactured in sufficient and reasonably available commercial quantities of a satisfactory quality are treated as domestic. Scrap generated, collected, and prepared for processing in the United States is considered domestic; or (ii) The end product is a COTS item. 48 C.F.R. 25.003.

11. To be a domestic end product, a product's components need not be wholly manufactured in the U.S. For COTS items, the origin and cost of components is irrelevant; the product need only be manufactured in the U.S.

12. U.S.-made end product means an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. 48 C.F.R. 25.003; 48 C.F.R. 52.225-5. To be a U.S.-made end product, an article need not be wholly the growth, product or

manufacture of the United States. To be a U.S.-made end product, an article manufactured in the United States need not be substantially transformed in the U.S.

13. Designated country end product means an article that -- (1) Is wholly the growth, product, or manufacture of a [designated] country; or (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a [designated] country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. 48 C.F.R. 25.003; 48 C.F.R. 52.225-5

14. The United States is not a designated country.

15. As noted by the FAR Council when the clause was rewritten, the effect of the clause is contractually "to permit the purchase of all U.S. made end products, whether or not they are domestic end products." 63 Fed. Reg. 51642. The clause does not make the purchase of products that are domestic end products impermissible.

Manufacture of Rosuvastatin Calcium Tablets in the United States

16. The Rosuvastatin Calcium Tablets end product supplied to the VA is manufactured in Dayton, New Jersey, in the United States.

17. Rosuvastatin Calcium Tablets are produced for Acetris by Aurolife Pharma LLC through a complicated manufacturing process that occurs in Aurolife's New Jersey facility that involves the combination of the Bulk Drug Substance with multiple inactive ingredients, including some intermediates that are mixed in to aid the conversion of the multiple ingredients and the safety and effectiveness of the Drug Product.

18. This is not a case in which bulk formulated drug product is manufactured from raw chemical active and inactive ingredients outside the U.S., imported and then measured and pressed into tablets, packaged and labeled in the U.S.

19. ANDA No. 079170 specifies the exact formulation that must be mixed and manufacturing processes that must be followed in order for the Rosuvastatin Calcium Tablets authorized by the ANDA to be marketed for use as a prescription drug. The manufacturing of Rosuvastatin Calcium Tablets employs processes that transform these ingredients into finished, medically safe and effective dosage tablets. The ANDA approves Rosuvastatin Calcium Tablets for use for the FDA Approved Indications, if manufactured in accordance with the formulation and processes specified in the ANDA.

20. This processing changes the properties and characteristics of the Bulk Drug Substance, materially enhancing the pharmacokinetics of the resulting Drug Product.

21. The process of converting these multiple ingredients into the Rosuvastatin Calcium Tablets that may be marketed commercially by the manufacturer for the FDA Approved Indications occurs entirely within the United States.

22. The ingredients processed in the United States are sourced from a variety of suppliers, both U.S. and foreign, including, among other ingredients: Lactose Monohydrate; Dibasic Calcium Phosphate; Microcrystalline Cellulose; Crospovidone; Magnesium Stearate; and active ingredient, rosuvastatin calcium.

23. HMG-CoA reductase inhibitors such as the Bulk Drug Substance are unstable under conditions of acidity, oxygen, light and humidity. That is, the potency constantly becomes less, and the Bulk Drug Substance degrades into other, separate chemicals,

including lactone, which is described in a separate Material Data Safety Sheet and is identified as harmful if swallowed.

24. For these reasons, extensive additional processing of the Bulk Drug Substance with other ingredients must occur to change the Bulk Drug Substance's properties and transform it into a stable Drug Product, with established potency, that meets all requirements for levels of impurity, including those produced as harmful degradation byproducts, and can be safely administered for the treatment of a human disease or condition.

25. Such processes and ingredients constitute a separate invention from the invention of rosuvastatin calcium – the Bulk Drug Substance – and are the subject of separate patents/applications required to address disintegration of rosuvastatin calcium, a property of the chemical that would, without application of the patented processed and ingredients, preclude the effective production of an effective and usable medicine containing rosuvastatin calcium. *See*, *e.g.*, US 6316460 B1; EP 2566465 A2 (application).

26. The multiple components utilized in the U.S.-based manufacturing process for Rosuvastatin Calcium Tablets that substantially transforms the raw chemical active and inactive ingredients Bulk Drug Substance include the following:

27. Microcrystalline cellulose, lactose monohydrate, and dibasic calcium phosphate anhydrous are added to the rosuvastatin calcium Bulk Drug Substance as adjuvant to improve the bioavailability/absorption, leading to pharmacokinetic profiles equivalent

to the brand product (Crestor®) for therapeutic equivalency, as required by the applicable FDA-approved ANDA.

28. By definition, adjuvants are pharmacological agents that modify the effect of other agents, in this case rosuvastatin calcium.

29. These excipients are blended according to a set protocol and blending times to ensure proper mixing throughout the blend resulting in a different character than is represented by the raw Bulk Drug Substance.

30. Dibasic Calcium Phosphate anhydrous is a key ingredient, addition of which results in a Drug Product with a higher pH than the Bulk Drug Substance, preventing the instability, variable potency and formation of hazardous degradation byproducts that would otherwise occur from the Bulk Drug Substance, significantly enhancing the stability of the finished product.

31. Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the manufacturing process. Lubricant mixing is carefully done to ensure that the drug release profile and pharmacokinetics is not influenced by this hydrophobic environment. This also changes the character of the end-product in a way that distinguishes it from the Bulk Drug Substance in its unprocessed state.

32. Finally, different colorings agents and film coating are added to give each strength a distinct name and character.

33. Film coating is performed using polymers which imparts a gives a protective barrier for each strength of the drug and also masks the taste, thereby modifying the use of the Bulk Drug Substance and making it appropriate for patient use.

34. Manufacturing of Rosuvastatin Calcium Tablets includes the following separate processes, all of which occur within the United States, that cause the substantial transformation of the Bulk Drug Substance and other ingredients into Rosuvastatin Calcium Tablets: testing of raw materials for potency; weighing the raw materials for discharge; milling and sifting; blending and lubrication; compression; coating suspension preparation; tablet coating; QC/QA testing and release; and packaging and labeling.

35. These processes require complex and expensive pieces of large-scale, industrial equipment costing hundreds of thousands of dollars.

36. The time necessary to manufacture each batch of Rosuvastatin Calcium Tablets is quite substantial and requires up to several days, depending on the size of the batch and the dosage strength of the tablets.

37. The cost of this processing is significantly more than the cost of purchasing the Bulk Drug Substance.

38. Further, because the Bulk Drug Substance cannot be marketed or used as a medicine and thus has no value or use as a consumer product, these processes produce a Drug Product with a value many times higher than that of the Bulk Drug Substance.

39. In other words, because the bulk rosuvastatin calcium chemical has no commercial use as a medicine, the increase in the market value of the Rosuvastatin Calcium Tablets

approved as a drug by the FDA is disproportionate to the incremental added cost of producing the Rosuvastatin Calcium Tablets from rosuvastatin calcium.

40. In addition, development of a Drug Product that is both safe and effective requires multiple levels of extensive clinical trials, filing of a New Drug Application or Abbreviated New Drug Application, and approval by the FDA in a process that may cost millions or hundreds of millions of dollars and can take years.

The Manufacture and Marketing of Prescription Drugs Is Heavily Regulated and the Raw Chemical Ingredients of Such Drugs Cannot Be Marketed As Medicine

41. The FDA regulates sale of Drug Products and Bulk Drug Substance in the U.S. pursuant to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. 301 *et seq*.

42. Pursuant to the FFDCA and FDA's implementing regulations, raw chemical ingredients of prescription drugs, including Bulk Drug Substances, like rosuvastatin calcium, are distinct articles from Drug Products, like Rosuvastatin Calcium Tablets. 21 C.F.R. 210.3.

43. FDA regulations define Components of Drug Products to include Bulk Drug Substances. *Id.* Specifically, "Component" means any ingredient intended for use in the manufacture of a Drug Product, including those that may not appear in such Drug Product. 21 C.F.R. 210.3.

44. FDA defines Bulk Drug Substance as active pharmaceutical ingredient ("API") which means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any

function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance. 21 C.F.R. 207.1.

45. FDA requires that a unique National Drug Code be assigned to every Drug Product such as Rosuvastatin Calcium Tablets. The NDC enables the FDA to trace the product to the manufacturer authorized to make the product under the approval authority. Each form and strength of a drug must be separately approved and identified by a distinct NDC. The FDA prohibits the same NDC assigned to a Drug Product from being used to identify a Bulk Drug Substance, such as rosuvastatin calcium, that has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease condition. There may be multiple manufacturers of Rosuvastatin Calcium Tablets, but each must be authorized to manufacture the drug by a New Drug Approval or an ANDA at an FDA-approved facility. The manufacturer must adhere strictly to the precise formulation in the approval authority, including both active and inactive ingredients, and specified manufacturing processes required to make the Drug Product safe and effective. The FDA requires that the name of the Drug Product (in this case Rosuvastatin Calcium Tablets) appear on every Drug Product label and prohibits use of that name on the label for the component Bulk Drug Substance (in this case, rosuvastatin calcium).

46. Pursuant to 21 C.F.R. 201.56, the Drug Product, Rosuvastatin Calcium Tablets, is required to be labelled with each of 45 specified elements of information in a specified order. Complaint Exhibit 1, Attachment 1, Rosuvastatin Calcium Tablets Label.

47. The labeling requirements for drug products and bulk drug substances are very different, and the multi-page label required for the Drug Product bears no resemblance to the label for the Bulk Drug Substance, rosuvastatin calcium, which is a producer product that cannot be used to treat a human disease or condition.

48. On the other hand, because Bulk Drug Substances are intended only for use by producers and may not be sold to consumers, pursuant to FDA regulations, the label for the raw chemical active ingredient, rosuvastatin calcium, bears no resemblance to the Rosuvastatin Calcium Tablets label. Instead, the label is a simple sticker required to contain the following brief statement: "Caution: For manufacturing, processing, or repacking," as well as "Rx only." 21 U.S.C. 201.122. Complaint Exhibit 1, Attachment 2, shipping label for Bulk Drug Substance, rosuvastatin calcium.

49. Bulk Drug Substances are regulated by the Occupational Safety and Health Administration ("OSHA") Hazard Communication Standard, 29 C.F.R. 1910.1200, applicable to industrial chemicals, which requires that information of an entirely different sort be provided by the chemical manufacturer to the importer on a Material Safety Data Sheet in a standard form, equally detailed as the FDA labeling requirements for Drug Products, but addressing issues such as flammability, explosive limits, fire-fighting measures, first-aid measures, protective equipment, accidental release measures, etc. under 16 required headings and 67 required subheadings. 29 C.F.R. 1910.1200, Appendix D. Complaint Exhibit 1, Attachment 3, MSDS for rosuvastatin calcium.

50. FDA does not approve Bulk Drug Substance for treatment of a disease or condition, does not require demonstration of either safety or efficacy, and does not place the same regulatory requirements on manufacturers of Bulk Drug Substances as it does on manufacturers of Drug Products. To the contrary, FDA exercises limited oversight of the Bulk Drug Substance and only to the extent that it requires that the chemical be made by the Bulk Drug Substance manufacturer identified in the Drug Product manufacturer's application to FDA and may inspect Bulk Drug Substance manufacturer sites to ensure the chemical is manufactured consistent with Current Good Manufacturing Practices ("cGMP").

51. Because Bulk Drug Substances have not been proven safe and efficacious for the treatment of any human disease condition, the FFDCA strictly prohibits sale of all Bulk Drug Substances, including rosuvastatin calcium, by manufacturers, for dispensing or administration to patients. It is a crime to market a Bulk Drug Substance for the same use as a Drug Product for which it may be an ingredient.

The Active Ingredient in Rosuvastatin Calcium Tablets Is a Producer's Product Not a Consumer's Product

52. The active ingredient in Rosuvastatin Calcium Tablets is a producer's product, not a consumer's product.

53. Health care providers and patients, who are consumers, do not purchase the raw chemical that becomes the active ingredient in Rosuvastatin Calcium Tablets for dispensing to patients in the treatment of any human disease condition.

54. Pharmaceutical manufacturers, who are producers, purchase the active ingredient in Rosuvastatin Calcium Tablets from chemical manufacturers as an ingredient in the manufacture of a prescription drug, Rosuvastatin Calcium Tablets, which can be sold to consumers for use in the treatment of a human disease condition.

55. The FFDCA strictly prohibits sale of all Bulk Drug Substances, including rosuvastatin calcium, by manufacturers to consumers, for dispensing or administration to patients.

56. Under the FFDCA, Bulk Drug Substance manufacturers may only sell Bulk Drug Substances for use for further processing and manufacturing by producers – either by a manufacturer or compounding pharmacy – or for research.

57. The distinction between Bulk Drug Substance as a producers' product and Drug Product as a consumers' product is further apparent from the labeling for the two substances. Only the Drug Product label contains required data informing consumers of the properties of the Drug Product in relation to its use as a medicine in the treatment of human disease. If Rosuvastatin Calcium Tablets indicated they were products of India, the country from which the Bulk Drug Substance was sourced, consumers would likely be misled into thinking the processes required to make the Drug Product safe and effective occurred in India rather than the United States.

The Request for Final Determination and Final Decision

58. On July 7, 2017, in response to a cure notice from the VA to Acetris relating to its contract, Acetris submitted a request for final determination to CBP pursuant to 19 C.F.R. 177.28(b) regarding the government procurement of Rosuvastatin Calcium

Tablets 5 mg, Rosuvastatin Calcium Tablets 10 mg, Rosuvastatin Calcium Tablets 20 mg, and Rosuvastatin Calcium Tablets 40 mg manufactured in the U.S.

59. Specifically, Acetris requested a final determination regarding whether the Company's Rosuvastatin Calcium Tablets products comply with 48 C.F.R. 52.225-5, which governs the Company's sale of Rosuvastatin Calcium Tablets to the VA under its contract, considering, as the Clause requires, both whether the products are U.S.-made end products manufactured in the U.S. and, separately, whether the products are substantially transformed in the U.S. In the alternative, Acetris requested that, if CBP lacked jurisdiction to determine whether the products were U.S.-made end products manufactured in the U.S. as those terms are used in 48 C.F.R. 52.225-5, CBP make an explicit finding to that effect.

60. In its submission (Complaint Exhibit 1), supplemental filing (Complaint Exhibit 2), and subsequent written follow ups (Complaint Exhibit 3), and in oral communications, including at a formal August 8, 2018 meeting with CBP, Acetris provided information regarding the complex, expensive and time consuming nature of the process for manufacturing Rosuvastatin Calcium Tablets from raw chemical active and inactive ingredients, the regulated nature of the manufacture and marketing of prescription drugs, the location of the Rosuvastatin Calcium Tablets manufacturing operation in the United States, the nature of the raw chemical Bulk Drug Substance as only a producers' product, the relative cost of manufacturing and value of raw chemical Bulk Drug Substance and the Drug Product manufactured from raw chemical active and inactive ingredients, the distinct labelling requirements applicable to raw chemical Bulk Drug

Substance and Drug Products manufactured from raw chemical active and inactive ingredients, the unique name and numbering associated with Rosuvastatin Calcium Tablets as distinct from the raw chemical Bulk Drug Substance, and country of origin information for all raw chemical active and inactive ingredients.

61. With the submission of the July 7, 2017 ruling request and all subsequent submissions prior to Customs issuance of a Final Determination, Acetris provided all information necessary for CBP to issue a Final Determination regarding the U.S. manufacture and U.S. substantial transformation of Rosuvastatin Calcium Tablets for purposes of government procurement.

62. On February 5, 2018, CBP published in the Federal Register a Notice of Issuance of Final Determinations Concerning Certain Pharmaceutical Products concerning the country of origin of these certain pharmaceutical products, including Rosuvastatin Calcium Tablets, as well as the place of manufacture of these products. 83 Fed. Reg. 5118-5120. A copy of the Final Determination, which is challenged in this action, is attached to this Complaint as Complaint Exhibit 4. All further quotations in paragraphs 63-79 of this Complaint are taken from 83 Fed Reg. 5118–5120 unless otherwise cited.

63. According to the Final Determination, which is the best evidence of its contents, "Aurolife manufactures the Rosuvastatin Calcium tablets supplied to Acetris in a U.S. Food & Drug Administration ("FDA") approved cGMP compliant manufacturing facility, located in Dayton, NJ, [United States,] from several active and inactive ingredients procured domestically and abroad."

64. According to the Final Determination, which is the best evidence of its contents, the processing that occurs in the United States includes the following:

"Microcrystalline cellulose, lactose monohydrate, and dibasic calcium phosphate anhydrous are added to the Rosuvastatin Calcium API as adjuvant to improve the bioavailability/absorption, leading to pharmacokinetic profiles equivalent to the brand product (Crestor®) for therapeutic equivalency. These four excipients are blended according to a set protocol and blending times to ensure proper mixing. Dibasic Calcium Phosphate anhydrous is a key ingredient, addition of which results in a drug product with a higher pH than the API, preventing the instability, variable potency and formation of hazardous degradation byproducts that otherwise are present in the API, significantly enhancing the stability of the finished product."

65. "Magnesium stearate is added to create a hydrophobic environment around particles which provides a lubrication effect during the production process. Lubricant mixing is carefully done to ensure that the drug releasing profile and pharmacokinetics are not influenced by this hydrophobic environment."

66. "Finally, different coloring agents and film coating are added to give each strength a distinct name and character. Film coating is performed using polymers which impart a protective barrier for each strength of the drug and to mask the taste."

67. The Final Determination acknowledges that Acetris provided a "a manufacturing flow chart depicting the various steps which occur in the United States to make the final Rosuvastatin Calcium tablets" and does not dispute the accuracy of the chart, which indicates that manufacture of Rosuvastatin Calcium Tablets in the United States

requires steps including testing of raw materials for potency, weighting the raw materials for discharge, milling, sifting, blending, lubrication, compression, coating suspension preparation, tablet coating, QC/QA Testing and Release, and packaging and labeling.

68. The Final Determination acknowledges but does not evaluate Acetris's statements that: the FDA requires that a unique National Drug Code ("NDC") be assigned to every Drug Product such as Rosuvastatin Calcium tablets, but prohibits that same NDC from being associated with any API, such as rosuvastatin calcium; that raw chemical active ingredient has not been demonstrated to be safe and effective and cannot be sold for the treatment of any human disease or condition; and that the FDA requires the name of the drug product (Rosuvastatin Calcium Tablet) to appear on every Drug Product label and prohibits use of that name on the label for the API. The Final Determination does not dispute any of these statements.

69. The Final Decision acknowledges but neither evaluates nor disputes Acetris's statement that the raw chemical active ingredient in Rosuvastatin Calcium Tablets is intended only for use by producers for further processing or for research since it is unstable and not fit for medical use and may not be sold to consumers to treat a disease or condition.

70. The Final Decision acknowledges but neither evaluates nor disputes Acetris's statement that the raw chemical active ingredient in Rosuvastatin Calcium Tablets degrades so as to both reduce potency and create hazardous byproducts.

71. The Final Determination does not evaluate the complexity of the manufacturing functions performed by Acetris.

72. The Final Determination neither acknowledges nor evaluates information provided by Acetris regarding the relative cost of manufacturing and value of raw chemical Bulk Drug Substance and the Drug Product manufactured from raw chemical active and inactive ingredients and approved by the FDA for use as a drug.

73. In the Final Determination, CBP states that its Laboratories and Scientific Services Directorate informed it that "the imported API, Rosuvastatin Calcium, retains its chemical and physical properties upon processing in the United States. Increasing the stability of the API and standardizing its concentration do not change the API. Further, the processing performed in the United States does not affect the medicinal use of the API."

74. In the Final Determination, CBP states that "[b]ased on the information presented, the API does not undergo a change in name, character or use" and that, therefore, "no substantial transformation occurs in United States, and the Rosuvastatin Calcium Tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement."

75. In the Final Determination, CBP provides no rationale for its conclusion that the unique name and numbering of Rosuvastatin Calcium Tablets fail to constitute a substantial transformation, particularly given the critical health and safety need and legal requirement to distinguish, by name, number and labelling, raw chemical Bulk Drug Substance, a producer product, from manufactured Drug Product, a consumer product.

76. In the Final Determination, CBP erred in concluding that the raw chemical active ingredient has a medicinal use and that the commercial use of Rosuvastatin Calcium

Tablets is the same as the use of the raw chemical active ingredient. CBP provides no rationale for this conclusion, other than to say that its Laboratories and Scientific Services Directorate concluded this based on identification of the active chemical's molecule in the Drug Product, and provides no rationale for the Directorate's conclusion.

77. In the Final Determination, CBP makes no claim that Rosuvastatin Calcium Tablets are the same article of commerce as the raw chemical active ingredient used in the formulation and manufacture of that Drug Product.

78. In the Final Determination, CBP improperly states that "[t]he term "manufactured in the United States" in the definition of U.S.-made end product in 48 C.F.R. § 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides [under the Trade Agreements Act] that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality" (emphasis added) even though the definition of U.S.-made end product in 48 C.F.R. § 25.003 does not require a product be wholly the manufacture of the United States. In the Final Determination, CBP neither acknowledges nor addresses the differences in the language used in the FAR to define U.S.-made end product and designated country end product, including their origins in separate statutory schemes.

79. As a result, the Final Determination concludes that "we do not find that [Rosuvastatin Calcium Tablets] are manufactured in the United States."

VI. SPECIFIC COUNTS

COUNT I

80. Paragraphs 1 through 79 and Complaint Exhibits 1-4 are incorporated by reference as though fully set forth therein.

81. Rosuvastatin Calcium Tablets undergo a substantial transformation in the U.S. because they are the product of a complex, time consuming and expensive manufacturing process that transforms the active and inactive ingredients into a distinct prescription Drug Product.

82. Rosuvastatin Calcium Tablets undergo a substantial transformation in the U.S. because the manufacturing process occurring in the U.S. transforms active and inactive ingredients that are producer goods unfit for human consumption as a drug into a prescription drug that is a consumer good with a different use, that is, a medicine that can be dispensed for treatment of human disease or condition.

83. Rosuvastatin Calcium Tablets have a new and different use from the raw chemical active and inactive ingredients used in manufacturing this drug because the manufacture and marketing of prescription drugs is regulated by the FDA, which prohibits the marketing and sale of the raw chemical active and inactive ingredients for use in treating any human disease or condition but permits the Drug Product to be marketed and sold for its FDA Approved Indications.

84. The Final Determination incorrectly found that no substantial transformation occurred when raw chemical active and inactive ingredients sourced from the U.S. and foreign countries were manufactured into Rosuvastatin Calcium Tablets in the U.S.

85. The Final Determination incorrectly found that the raw chemical active ingredient in the Drug has a medicinal use, and that Rosuvastatin Calcium Tablets which are formulated

in accordance with the FDA's drug approval authority and are used to treat specific human diseases and conditions do not have a different use from their raw chemical active ingredient, which cannot be used to treat any human disease or condition.

86. Accordingly, the Court should reverse CBP's ruling and hold that Rosuvastatin Calcium Tablets are a product of the U.S.

COUNT II

87. Paragraphs 1 through 86 and Complaint Exhibits 1-4 are incorporated by reference as though fully set forth therein.

88. Rosuvastatin Calcium Tablets are manufactured in the U.S.

89. The Final Determination states that Rosuvastatin Calcium Tablets are manufactured in the U.S.

90. Every manufacturing step identified in the ANDA and required by the FDA to convert raw chemical active and inactive ingredients into usable Drug Product occurs in the U.S.

91. These steps are complex, time consuming and expensive and constitute far more than simple assembly.

92. There is no requirement that, to be considered manufactured in the U.S. within the meaning of the FAR, the components of a COTS item like Rosuvastatin Calcium Tablets have to be substantially transformed in, or products of, the U.S.

93. The Final Decision improperly equates the manufacture test in FAR 52.225-5, applicable to U.S.-made end products, of which domestic end products under the BAA

are a subset, with the separate and different TAA "wholly manufactured" test used to determine foreign products eligible for a TAA waiver of the BAA procurement preferences when a product is not U.S. made.

94. The Final Decision therefore improperly concludes, from the fact that Rosuvastatin Calcium Tablets are not wholly manufactured in the U.S., components included, that the Drug Product is not manufactured in the U.S.

95. Accordingly, the Court should reverse CBP's ruling and hold that Rosuvastatin Calcium Tablets are manufactured in the U.S.

ALTERNATIVE COUNT III

96. Paragraphs 1 through 95 and Complaint Exhibit 1-4 are incorporated by reference as though fully set forth therein.

97. CBP is statutorily authorized to issue advisory rulings and final determinations on whether, under section 2518(4)(B) of Title 19 of the United States Code, an article is or would be a product of a designated (foreign) country or instrumentality.

98. That section provides that an article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

99. CBP has no authority to issue binding decisions on whether a product, which is not wholly the manufacture of a foreign country, is properly characterized as manufactured in the U.S. under FAR Clause 52.225-5, set forth in a VA contract for procurement of prescription drugs, because all manufacturing processes applied to components necessary to produce the end product occurs in the U.S. regardless of the source of the components.

100. The substantial transformation rule of origin under the TAA used to waive the Buy American Act preference for domestic end products stands in contrast to the rule of origin that applies the preference under the Buy American Act. "The disparity between the applicable rules of origin under the TAA and the BAA is not without consequence." *Xerox Corp. v. U.S.*, 753 F.Supp.2d 1355 (C.I.T. 2011).

101. Domestic end products are a subset of U.S.-made end products manufactured in the U.S.

102. A product does not need to be wholly manufactured in the U.S., components included, to be deemed manufactured in the U.S.

103. Even if a ruling that a product is or is not substantially transformed in the U.S. arguably is within the TAA's grant of statutory authority, because such a ruling is determinative, in the negative, of whether the "article is or would be a product of a foreign country or instrumentality designated pursuant to" the TAA, a ruling by CBP that a product is or is not manufactured in the U.S. has no bearing on the issue of whether the same product could also be deemed substantially transformed in a designated country were a TAA waiver somehow needed.

104. CBP's ruling that Rosuvastatin Calcium Tablets are not manufactured in the United States is ultra vires, and the Court should rule that CBP lacked authority to issue this decision and remand the decision to CBP to strike the affected language.

PRAYER FOR RELIEF

Wherefore, plaintiff Acetris Health, LLC, respectfully prays that this Court enter judgment in its favor; find that prescription drugs such as Rosuvastatin Calcium Tablets are highly regulated and articles cannot be marketed or distributed as drugs unless manufactured in accordance with the specific formulation and processes specified in the FDA drug approval authority; that FDA regulations prohibit marketing of any of the ingredients of Rosuvastatin Calcium Tablets for use in treating a human disease or condition but permit the marketing of Rosuvastatin Calcium Tablets for specific diseases and conditions; that none of the ingredients of Rosuvastatin Calcium Tablets in their raw state have been demonstrated safe and effective for treating a human disease or condition but that Rosuvastatin Calcium Tablets manufactured in accordance with the formulation and processes specified in the ANDA have been demonstrated safe and effective for treating specific diseases and conditions; that the drug approval authority to market Rosuvastatin Calcium Tablets gives that product a commercial value significantly greater than that of the active chemical ingredient; that Rosuvastatin Calcium Tablets are produced through complex, time consuming manufacturing processes using expensive equipment; that these manufacturing processes adds considerably to the cost of the drug and disproportionately more so to the value of the drug compared to the value of its ingredients; that the chemical ingredients of Rosuvastatin Calcium Tablets are producers' products with a use only in the manufacturing process; that none of the chemical ingredients in Rosuvastatin Calcium Tablets

are consumer products purchased by health care providers or patients to treat any human disease or condition; and that for all these reasons, separately and together, the imported raw chemical active and inactive ingredients of Rosuvastatin Calcium Tablets undergo a change in name, character or use and are substantially transformed in the United States when manufactured into Rosuvastatin Calcium Tablets. In addition, Acetris Health, LLC, prays that this Court find that Rosuvastatin Calcium Tablets are U.S.-made end products within the meaning of 48 C.F.R. 52.225-5 because they are manufactured in the United States or, in the alternative, that CBP lacked jurisdiction to decide this issue. Finally, Acetris Health, LLC, prays that this Court grant plaintiff such further and additional relief as this Court may deem proper.

Respectfully Submitted,

s/Stephen E. Ruscus

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