STATE OF OREGON
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
DIVISION OF FINANCIAL REGULATION

In the Matter of: Eugia US LLC (*fka* AuroMedics Pharma, LLC), Respondent.	Case No. DPT-23-0028 ORDER ASSESSING CIVIL PENALTIES AND CONSENT TO ENTRY OF ORDER

The Director ("Director") of the Department of Consumer and Business Services for the State of Oregon ("Department"), acting by and through the Division of Financial Regulation ("Division") and in accordance with Oregon Revised Statutes ("ORS") 646A.680 through 646A.692 and the rules promulgated thereunder, known as the Prescription Drug Price Transparency Act (the "Act"), has determined that Eugia US LLC ("Eugia"), formerly AuroMedics Pharma, LLC (collectively "Respondent"),[1] engaged in activities that violated the Act.

Respondent wishes to resolve and settle this matter with the Director.

Now, therefore, as evidenced by the authorized signatures subscribed on this Order, Respondent hereby CONSENTS to entry of this Order upon the Director's Findings of Fact and Conclusions of Law as stated hereinafter.

FINDINGS OF FACT

The Director FINDS that:

1. Respondent is registered with the Department as a manufacturer under the Prescription Drug Price Transparency Act. The registry number assigned to Respondent by the Department is iReg number 42792.

[1] In the course of the events at issue in this Order, AuroMedics Pharma LLC changed its name to Eugia US LLC. For purposes of this Order the name "Respondent" will be used to refer to the Respondent both before and after this name change.

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2. Respondent's business address is 279 Princeton Highstown Road, East Windsor, NJ 08520.

3. Respondent's company representative as listed in iReg is Julia Faria ("Faria")—Respondent's Senior Director of Sales Operations and Administration.

4. Respondent is a manufacturer of prescription drugs that are *available for sale in this state.* The drugs that are the subject of this matter (the "Subject Drugs") include:

A.	Cyclophosphamide	NDC[2] 55150-271-01
B.	Isoproterenol Hydrochloride (.2 mg/mL)	NDC 55150-316-25
C.	Isoproterenol Hydrochloride (1 mg/5 mL)	NDC 55150-317-10
D.	Arsenic Trioxide	NDC 55150-366-10
E.	Pemetrexed	NDC 55150-383-01
F.	Vasopressin	NDC 55150-371-25
G.	Esmolol Hydrochloride (10 mg/ mL)	NDC 55150-420-10
H.	Esmolol Hydrochloride (20 mg/mL)	NDC 55150-421-10
I.	Dactinomycin (.5 mg/mL)	NDC 55150-431-01
J.	Dactinomycin (.5 mg/mL)	NDC 55150-928-02
K.	Bortezomib	NDC 55150-337-01
L.	Dexmedetomidine HCl	NDC 55150-297-10
M.	Acetaminophen (10 mg/mL)	NDC 55150-307-24

[2] The "NDC" is the National Drug Code listed with the Federal Drug Administration ("FDA") for an individual product.

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N.	Chlorpromazine HCl	NDC 55150-318-25

5. Each of the Subject Drugs was introduced for sale in the United States at a price that exceeded the threshold established by the Centers of Medicare and Medicaid Services for specialty drugs in the Medicare Part D program.

Subject Drug (A)

6. Respondent filed a new specialty drug report with the Department for Subject Drug (A) on December 16, 2021.

7. In the report for Subject Drug (A), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (A). Specifically, Respondent repeated the verbiage Respondent had provided for a different data element—"Marketing Description"—and did not report any pricing information relative to Subject Drug (A).

8. On January 31, 2022, the Department made a written request for information ("RFI") to Respondent, requesting additional information regarding the pricing methodology used with respect to Subject Drug (A), and required that Respondent provide a response within 60 days.

9. 60 days from the date of the RFI elapsed on April 1, 2022.

10. Respondent did not respond to the Department's RFI.

Subject Drug (B)

11. Respondent filed a new specialty drug report with the Department for Subject Drug (B) on December 16, 2021.

12. In the report for Subject Drug (B), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (B). Specifically, Respondent repeated the verbiage Respondent had provided for a different data element—"Marketing Description"—and did not report any pricing information relative to Subject Drug (B).

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13. On January 31, 2022, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (B), and required that Respondent provide a response within 60 days.

14. 60 days from the date of the RFI elapsed on April 1, 2022.

15. Respondent did not respond to the Department's RFI.

Subject Drug (C)

16. Respondent filed a new specialty drug report with the Department for Subject Drug (C) on December 16, 2021.

17. In the report for Subject Drug (C), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (C). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (C).

18. On January 31, 2022, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (C), and required that Respondent provide a response within 60 days.

19. 60 days from the date of the RFI elapsed on April 1, 2022.

20. Respondent did not respond to the Department's RFI.

Subject Drug (D)

21. Respondent filed a new specialty drug report with the Department for Subject Drug (D) on May 18, 2022.

22. In the report for Subject Drug (D), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (D). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (D).

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23. On June 22, 2022, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (D), and required that Respondent provide a response within 60 days.

24. 60 days from the date of the RFI elapsed on August 21, 2022.

25. Respondent did not respond to the Department's RFI.

Subject Drug (E)

26. Respondent filed a new specialty drug report with the Department for Subject Drug (E) on June 24, 2022.

27. In the report for Subject Drug (E), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (E). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (E).

28. On July 22, 2022, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (E), and required that Respondent provide a response within 60 days.

29. 60 days from the date of the RFI elapsed on September 20, 2022.

30. Respondent did not respond to the Department's RFI.

Subject Drug (F)

31. Respondent filed a new specialty drug report with the Department for Subject Drug (F) on July 15, 2022.

32. In the report for Subject Drug (F), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (F). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (F).

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33. On August 1, 2022, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (F), and required that Respondent provide a response within 60 days.

34. 60 days from the date of the RFI elapsed on September 30, 2022.

35. Respondent did not respond to the Department's RFI.

Subject Drug (G)

36. Respondent filed a new specialty drug report with the Department for Subject Drug (G) on September 16, 2022.

37. In the report for Subject Drug (G), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (G). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (G).

38. On September 20, 2022, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (G), and required that Respondent provide a response within 60 days.

39. 60 days from the date of the RFI elapsed on November 19, 2022.

40. Respondent did not respond to the Department's RFI.

Subject Drug (H)

41. Respondent filed a new specialty drug report with the Department for Subject Drug (H) on September 16, 2022.

42. In the report for Subject Drug (H), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (H). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (H).

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43. On September 20, 2022, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (H), and required that Respondent provide a response within 60 days.

44. 60 days from the date of the RFI elapsed on November 19, 2022.

45. Respondent did not respond to the Department's RFI.

Subject Drug (I)

46. Respondent filed a new specialty drug report with the Department for Subject Drug (I) on March 15, 2023.

47. In the report for Subject Drug (I), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (I). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (I).

48. In addition, Respondent left the fields provided to identify the acquisition costs and acquisition date of Drug (I) blank. Manufacturers are required to provide data in these fields when drugs are acquired, rather than developed.

49. On March 20, 2023, 2023, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (I), and required that Respondent provide a response within 60 days.

50. On May 26, 2023 Respondent provided information responsive to the Department's initial RFI. However, at this time Respondent indicated for the first time that Respondent had acquired Drug (I), rather than developing it.

51. On May 31, 2023, the Department made a follow-up RFI for information relating to the acquisition costs of Drug (I) and the date of acquisition.

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52. On June 2, 2023, Respondent responded to the follow-up RFI to ask whether those questions had already been answered. Respondent did not provide any further information.

53. 60 days from the date of the follow-up RFI elapsed on July 30, 2023.

Subject Drug (J)

54. Respondent filed a new specialty drug report with the Department for Subject Drug (J) on March 15, 2023.

55. In the report for Subject Drug (J), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (J). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (J).

56. In addition, Respondent left the fields provided to identify the acquisition costs and acquisition date of Drug (J) blank. Manufacturers are required to provide data in these fields when drugs are acquired, rather than developed.

57. On March 20, 2023, 2023, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (J), and required that Respondent provide a response within 60 days.

58. On May 26, 2023 Respondent provided information responsive to the Department's initial RFI. However, at this time Respondent indicated for the first time that Respondent had acquired Drug (J), rather than developing it.

59. On May 31, 2023, the Department made a follow-up RFI for information relating to the acquisition costs of Drug (J) and the date of acquisition.

60. On June 2, 2023, Respondent responded to the follow-up RFI to ask whether those questions had already been answered. Respondent did not provide any further information.

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61. 60 days from the date of the follow-up RFI elapsed on July 30, 2023.

Subject Drug (K)

62. Respondent filed a new specialty drug report with the Department for Subject Drug (K) on April 27, 2023.

63. In the report for Subject Drug (K), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (K). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (K).

64. On May 1, 2023, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (K), and required that Respondent provide a response within 60 days.

65. 60 days from the date of the RFI elapsed on June 30, 2023

66. Respondent did not respond to the Department's RFI.

Subject Drug (L)

67. Respondent filed a new specialty drug report with the Department for Subject Drug (L) on April 28, 2023.

68. In the report for Subject Drug (L), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (L). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (L).

69. On May 1, 2023, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (L), and required that Respondent provide a response within 60 days.

70. 60 days from the date of the RFI elapsed on June 30, 2023.

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71. Respondent did not respond to the Department's RFI.

Subject Drug (M)

72. Respondent filed a new specialty drug report with the Department for Subject Drug (M) on May 17, 2023.

73. In the report for Subject Drug (M), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (M). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (M).

74. On May 22, 2023, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (M), and required that Respondent provide a response within 60 days.

75. 60 days from the date of the RFI elapsed on July 21, 2023

76. Respondent did not respond to the Department's RFI.

Subject Drug (N)

77. Respondent filed a new specialty drug report with the Department for Subject Drug (N) on May 17, 2023.

78. In the report for Subject Drug (N), Respondent failed to include information requested by the Department relating to pricing methodology used to establish the price of Subject Drug (N). Specifically, Respondent wrote "proprietary" in the field provided for reporting pricing information and did not report any pricing information relative to Subject Drug (N).

79. On May 22, 2023, the Department made an RFI to Respondent for additional information regarding the pricing methodology used with respect to Subject Drug (N), and required that Respondent provide a response within 60 days.

80. 60 days from the date of the RFI expired on July 21, 2023.

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81. Respondent did not respond to the Department's RFI.

Department Efforts to Secure Compliance

82. On October 11, 2022, the Department issued Noncompliance Letters ("the October 11, 2022 NC Letters") to Respondent pertaining to Subject Drugs (A) through (F), wherein the Department identified Respondent's potential violations under the Act. The October 11, 2022 NC Letters gave Respondent 30 days to come into compliance with the Act or to provide an explanation for why it is already in compliance. The October 11, 2022 NC Letters warned that failure to comply within 30 days would result in enforcement action, including assessment of civil penalties.

83. Respondent failed to respond to the October 11, 2022 NC Letters. Therefore, on November 29, 2022, the Department contacted Faria and Nichole Capobianco—a third-party filer contracted by Respondent ("Capobianco")—about Respondent's failure to report the pricing information, as described in Paragraphs 6 through 35 above, and failure to respond to the October 11, 2022 NC Letters.

84. On December 7, 2022, Capobianco requested a meeting with the Department for herself and Faria to discuss bringing Respondent into compliance. The Department subsequently sent a meeting invitation for December 13, 2022, to Faria and Capobianco. Faria declined the invitation, and Capobianco attended the meeting on December 13, 2022, on behalf of Respondent.

85. On February 22, 2023, the Department issued an NC Letter relating to Subject Drugs (G) and (H) ("the February 22, 2023 NC Letter"). The February 22, 2023 NC Letter required that within 30 days from the date of the letter that Respondent come into compliance with the Act or provide an explanation for why Respondent is already in compliance. The February 22, 2023 NC Letter warned that failure to comply within 30 days would result in enforcement action, including assessment of civil penalties.

86. Respondent failed to respond to the February 22, 2023 NC Letter.

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87. On May 11, 2023—after the due date for responding to the February 22, 2023 NC Letter—Faria requested a meeting with the Department. Respondent subsequently made revisions to the information reported about Subject Drugs (I) and (J), described in paragraphs 46-61, above.[3]

88. On September 6, 2023, the Department issued an NC Letter relating to Subject Drugs (I) through (N) ("the September 6, 2023 NC Letters"). The September 6, 2023 NC Letter required that within 30 days from the date of the letter that Respondent come into compliance with the Act or provide an explanation for why Respondent is already in compliance. The September 6, 2023 NC Letter warned that failure to comply within 30 days would result in enforcement action, including assessment of civil penalties.

89. Respondent failed to respond to the September 6, 2023 NC Letter.

CONCLUSIONS OF LAW

The Director CONCLUDES:

Violation of ORS 646A.689

90. Under ORS 646A.689(1)(h), Subject Drugs (A) through (N) are "prescription drugs."

91. Under ORS 646A.689(1)(e), Respondent is a "manufacturer."

92. Under ORS 646A.689(6), Respondent was required to provide the Department with the information described in ORS 646A.689(6)(a)-(f) for Subject Drugs (A) through (N) "no later than 30 days after" introducing each such drug for sale in the United States.

93. Respondent violated ORS 646A.689(6) when it failed to include information about the pricing methodology used to establish the price of Subject Drugs (A) through (N), or provided incomplete information regarding the same.

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[3] At this time Respondent also provided information responsive to the Department's then-outstanding RFI for a another drug—Medroxyprogesterone Acetate, NDC 55150-329-25—which is not at issue in this Order.

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94. Under ORS 646A.689(7), the Department was authorized to send the RFIs described in Paragraphs 8, 13, 18, 23, 28, 33, 38, 43, 49, 57, 64, 69, 74 and 79 above, requesting supporting documentation or additional information from Respondent concerning its reports for Subject Drugs (A) through (N).

95. Under OAR 836-200-0535(3), a prescription drug manufacturer must provide "a full and complete written response" within 60 days of receiving an RFI from the Department pursuant to ORS 646A.689(7).

96. Respondent violated ORS 646A.689(7) and OAR 836-200-0535(3) by failing to timely, fully, and completely respond to the Department's RFIs relating to Subject Drugs (A) through (N) as described above.

Civil Penalty Authority

97. Under ORS 646A.689(8)(b) through (d), ORS 646A.692, and OAR 836-200-0560(2)(a) and (b), a manufacturer may be subject to a civil penalty for failing to provide all information required under the Act, for failing to respond in a timely manner to a written request by the Department for additional information under ORS 646A.689(7), and for providing inaccurate or incomplete information under the Act.

98. Under OAR 836-200-560(2)(a), the Director may impose civil penalties against Respondent for "failing to provide required information or providing inaccurate or incomplete information" in an amount up to $500 per day for the first 30 days of violation, and up to $1,000 per day for each day thereafter.

99. Under OAR 836-200-0560(2)(b), the Director may impose civil penalties against Respondent for "failing to respond in a timely manner to a written request by the department for additional information" in an amount up to $1,500 per day for the first 30 days of violation, and up to $3,000 per day for each day thereafter.

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ORDER

The Director issues the following ORDER:

Order Assessing Civil Penalties

100. Based upon the foregoing and as authorized by ORS 646A.689(8)(b) through (d), ORS 646A.692, and OAR 836-200-0560(2)(a) and (b), the Director ORDERS that Respondent be assessed a CIVIL PENALTY in the amount of $210,100 for violating ORS 646A.689(6) and (7) and OAR 836-200-0535(3), as follows:

	Drug Name and NDC #	**Drug Report Filed**	**RFI Date**	**RFI Response Due**	**Days Overdue**	**Civil Penalty Amount**
A.	Cyclophosphamide (NDC 55150-271-01)	12/16/2021	1/31/2022	4/1/2022	571	$28,550
B.	Isoproterenol Hydrochloride (.2 mg/mL) (NDC 55150-316-25)	12/16/2021	1/31/2022	4/1/2022	571	$28,550
C.	Isoproterenol Hydrochloride (1 mg/5 mL) (NDC 55150-317-10)	12/16/2021	1/31/2022	4/1/2022	571	$28,550
D.	Arsenic Trioxide (NDC 55150-366-10)	5/18/2022	6/22/2022	8/21/2022	429	$21,450
E.	Pemetrexed (NDC 55150-383-01)	6/24/2022	7/22/2022	9/20/2022	399	$19,950
F.	Vasopressin (NDC 55150-371-25)	7/15/2022	8/1/2022	9/30/2022	389	$19,450
G.	Esmolol Hydrochloride (10 mg/ mL) (NDC 55150-420-10)	9/16/2022	9/20/2022	11/19/2022	339	$16,950

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H.	Esmolol Hydrochloride (20 mg/mL) (NDC 55150-421-10)	9/16/2022	9/20/2022	11/19/2022	339	$16,950
I.	Dactinomycin (.5 mg/mL) (NDC 55150-431-01)	3/15/2023	3/20/2023 (original); 5/31/2023 (follow-up)	5/19/2023 (original); 7/30/2023 (follow-up)	86	$4,300
J.	Dactinomycin (.5 mg/mL) (NDC 55150-928-02)	3/12/2023	3/20/2023 (original); 5/31/2023 (follow-up)	5/19/2023 (original); 7/30/2023 (follow-up)	86	$4,300
K.	Bortezomib (NDC 55150-337-01)	4/27/2023	5/1/2023	6/30/2023	116	$5,800
L.	Dexmedetomidine HCl (NDC 55150-297-10)	4/28/2023	5/1/2023	6/30/2023	116	$5,800
M.	Acetaminophen (10 mg/mL) (NDC 55150-307-24)	5/17/2023	5/22/2023	7/21/2023	95	$4,750
N.	Chlorpromazine HCl (NDC 55150-318-25)	5/17/2023	5/22/2023	7/21/2023	95	$4,750

101. The Director hereby SUSPENDS $135,100 of the CIVIL PENALTY imposed against Respondent for a period of three years from the effective date of this Order, but only if Respondent complies with and satisfies all terms of this Order, including without limitation the following:

(a) Within 60 days of the execution of this Order:

(i) Respondent shall pay any sums owed to the Department by Respondent that were outstanding immediately prior to the execution of this Order;

(ii) Respondent shall conduct a diligent inquiry and review of Respondent's records to determine whether Respondent is marketing any drugs that Respondent is required to report to the

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Department under the Act that Respondent has not yet reported to Department; and, if Respondent identifies any such drugs, Respondent shall report the same to the Department;

(iii) Respondent shall deliver to the Department the following certification:

(A) Respondent shall certify that Respondent has made all payments required under paragraph 101(a) of this Order;

(B) Respondent shall certify that Respondent has conducted the inquiry and review required under paragraph 101(b) of this Order;

(C) Respondent shall certify (1) the name of each drug identified in the course of the inquiry and review required under paragraph 101(b) of this Order, and (2) the date on which such drug was reported to the Department; provided, however, that if Respondent identifies no drugs in the course of such inquiry and review, then Respondent shall certify the same; and

(D) Respondent's certification shall be signed by an authorized Officer of Respondent and shall contain a statement that, to the best of Respondent's knowledge, the information contained in Respondent's certification is accurate and complete.

(b) Eugia shall respond to all correspondence from the Department no later than the response deadline indicated in the correspondence from the Department. If the correspondence from the Department does not specify a response deadline, Eugia's response shall be due on the tenth business day following the date the correspondence from the Department was sent.

(c) Eugia shall timely pay all registration and filing fees assessed by the Department.

(d) Eugia shall not commit any further violations of the Act.

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102. The $135,100 suspended CIVIL PENALTY will be waived three years from the effective date of this Order, provided Eugia has complied with the foregoing Order terms and does not commit any further violations of the Act during the three year period.

103. The $75,000 non-suspended CIVIL PENALTY assessed herein against Eugia is due and payable at the time this Order is returned to the Division.

104. Eugia's failure to satisfy any term of this Order will render all suspended and non-suspended CIVIL PENALTIES immediately due and owing.

105. This Order is binding upon Eugia's successors and assigns.

106. This Order is a "Final Order" under ORS 183.310(6)(b). Subject to that provision, the entry of this Order does not limit other remedies that are available to the Director under Oregon law.

SO ORDERED this 14th day of August, 2024.

Andrew Stolfi, Director
Department of Consumer and Business Services

/s/ Dorothy Bean
Dorothy Bean, Chief of Enforcement
Division of Financial Regulation

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ENTITY CONSENT TO ENTRY OF ORDER

I, Mark Fedele, state that I am an officer of EUGIA US LLC and authorized to act on its behalf. I have read the foregoing Order and that I know and fully understand the contents hereof. I have been advised of EUGIA US LLC's right to a hearing and right to be represented by counsel in this matter. EUGIA US LLC voluntarily consents to the entry of this Order without any force or duress, expressly waiving any right to a hearing in this matter, as well as any rights to administrative or judicial review of this Order. EUGIA US LLC understands that the Director reserves the right to take further actions against it to enforce this Order or to take appropriate action upon discovery of other violations of ORS 646A.680 through 646A.692 by EUGIA US LLC. EUGIA US LLC will fully comply with the terms and conditions stated herein.

EUGIA US LLC understands that this Consent Order is a public document.

Signature: */s/ Mark Fedele*

Position Held: President, Eugia US

State of NJ

County of Mercer

Signed or attested before me on this 8th day of August, 2024.

By Richard M. Kelly.

/s/ Richard M. Kelly

Notary Public

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