Exhibit 6

Thank you Sandra, will do!

Zachary Smith
[Quoted text hidden]

Katherine Eban <ebanvf40@gmail.com> Mon, May 2, 2022 at 8:00 AM
To: "Williams, Sandra A" <SandraA.Williams@fda.hhs.gov>

Good Morning Sandra,

I hope all is well.

Please find attached a letter requesting the exhibitions mentioned in the documents you provided for this FOIA request.

Thank you,

Zachary Smith
[Quoted text hidden]

FDA FOIA Follow Up Exhibits.docx.pdf
90K

Williams, Sandra A <SandraA.Williams@fda.hhs.gov> Tue, May 3, 2022 at 8:13 AM
To: Katherine Eban <ebanvf40@gmail.com>

Good morning

Thanks for your email. I have forwarded your May 1, 2022 letter to the Division of FOIA for logging as a new FOIA request. For any future requests for exhibits or attachments associated with any previous requests please use the FDA.GOV FOIA request portal for submitting requests.

Thank you,

Sandra Williams

Government Information Specialist

Food and Drug Administration

Division of Information Disclosure Policy

FOIA Branch East

Sandraa.Williams@fda.hhs.gov

[Quoted text hidden]

Katherine Eban <ebanvf40@gmail.com> Mon, Jun 27, 2022 at 8:00 AM
To: "Williams, Sandra A" <SandraA.Williams@fda.hhs.gov>
Bcc: katherineeban@gmail.com

Hello Sandra,

Gmail

Katherine Eban <ebanvf40@gmail.com>

FDA Amended FOIA Response 2021-8591

Katherine Eban <ebanvf40@gmail.com> Mon, May 2, 2022 at 8:00 AM
To: "Williams, Sandra A" <SandraA.Williams@fda.hhs.gov>

Good Morning Sandra,

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Thank you,

Zachary Smith
[Quoted text hidden]

FDA FOIA Follow Up Exhibits.docx.pdf
90K

May 1, 2022

Sandra Williams
Government Information Specialist
Food and Drug Administration
Division of Information Disclosure Policy
FOIA Branch East
949.608.4466
Sandraa.Williams@fda.hhs.gov

Re: FDA Amended FOIA Response 2021-8591

Dear: Sandra Williams

Thank you again for sending over a portion of the documents regarding FOIA Response 2021-8591 over two emails on March 25, 2022.

Upon reading the documents, my team discovered references to many external documents in forms of "exhibits". These exhibits are documents that are included in our amended FOIA request. The exhibits are as follows—

From FOIA APPLIED DV SAW 2021-8591 EIR Medtronic Neuromodulation, Minneapolis MN 10-26-15_Redacted

Establishment Inspection Report FEI: 2182207

1(SMM) Interstate Commerce Documents for Restore serial number , 40 pages

2(SMM) Interstate Commerce documents for Restore serial number , 40 pages

3(SMM) Interstate Commerce documents for Activa serial number 46 pages

4(SMM) Organization Charts, 11 pages

5(SMM) 37086 Extension Drawing and bill of materials, 8 pages

6(SMM) REG09974

7(SMM) REG08165

8(SMM) GCAPA 1469, 38 pages

9(SMM) 2010 PPT presentation to marketing , 5 pages

10(SMM) NDHF005697346, 13 pages

11(SMM) CAPA 1469 REB Meeting Minutes, 2 pages

12(SMM) NDHF1241103711, 26 pages

13(SMM) NDHF1241125360, 7 pages

14(SMM) BOM 375504001N, 2 pages

15(SMM) List of Commercially released DBS Extensions, 1 page

16(SMM) REG08143, 6 pages

17(SMM) REG08145, 5 pages

18(SMM) REG08146, 4 pages

19(SMM) REG09479, 3 pages

20(SMM) REG32910, 33 pages

21(SMM) Response 1 dated 01152015, 19 pages

22(SMM) DBS Patient Therapy Guide M930496A , 96 pages

23(SMM) DBS Information for Prescribers M927893A, 23 pages

24(SMM) DBA Information For Prescribers Addendum M939155

25(SMM) List of DBS and SCS Labeling, 5 pages

26(SMM) DBS 37601 Implant Manual M929110A

27(SMM) DBS Implant Manual 3387 and 3389 Lead Kit M927780A, 24 pages

28(SMM) DBS Implant Manual 37085 Extension Kit M928980A, 28 pages

29(SMM) DBS Implant Manual 7482A Extension Kit M927852A, 26 pages

30(SMM) DBS Implant Manual 7483 Extension Kit M942382A, 20 pages

31(SMM) DBS Implant Manual 37086 Extension Kit M942384A, 22 pages

32(SMM) Response 2

33(SMM) PE700965839

34(SMM) PE700913390

35(SMM) PE700590713

36(SMM) PE700857141

37(SMM) PE700251883

38(SMM) PE700214644

39(SMM) PE700984574

40(SMM) PE701021847

41(SMM) PE700971743

42(SMM) PE700996366

43(SMM) PE700938638

44(SMM) PE700909885

45(SMM) REG08166 DBS MVD 092010 Baseline Apx G-P, 238 pages

46(SMM) QSY26686 PIA 565 Surgical Lead Used for Trialing Evaluation, 12 pages

47(SMM) Surgical Lead Implantation Guide UC200704947EN

48(SMM) Literature Review

49(SMM) SCS Implantable leads table

50(SMM) NonReportable for QSY26686

51(SMM) PE700442782

52(SMM) REG32058 Medical Safety Assessment 565 Trialing phase

53(SMM) List of website users

54(SMM) Issue Assessment CPA33370

55(SMM) QAD 040309 Quality Agreement, 19 pages

56(SMM) 023 Control of Nonconforming Product, 14 pages

57(SMM) QMS 1340 TLP Escalating Quality Issues Handling Nonconformances, 16 pages

58(SMM) QMS1340 TLP Ver 12, 16 pages

59(SMM) QMS17007 Post Market Issue Escalation, 24 pages

60(SMM) DOC1088 Neuromodulation Product Deviation Authorization, 14 pages

61(SMM) DOC1018 Product Hold Order PHO Procedure, 14 pages

62(SMM) QSY19734 Ver 6 07302014 PIA Orientation in Model 37081 and 7472 Extensions,

63(SMM) QSY19734 Ver 5 06182014, 12 pages

64(SMM) NDHF0017-83143 Evaluation Test Report LZ Octad Ver 4 11052007, 44 pages

65(SMM) A74671 Deviation Authorization, 4 pages

66(SMM) 37081 Inventory 7272 total, 3 pages

67(SMM) Change Control Plan Mfg Site Reloc 04302014, 16 pages

68(SMM) ECO 1403034 Finished 10232014, 4 pages

69(SMM) QSY28809 Ver 4 08262015 PIA, 8 pages

70(SMM) Drawings M943324A and 502343, 6 pages

71(SMM) Where used M943324A 502343, 4 pages

72(SMM) 35766 Bill Of Materials, 1 page

73(SMM) ECO 1103381, 19 pages

74(SMM) QSY32230 PIA U Clip 502343, 5 pages

75(SMM) PE700839570, 19 pages

76(SMM) PE700870139, 21 pages

77(SMM) Confirmed PEs QSY28809, 2 pages

78(SMM) QSY20026 Ver 5 06102014 Causing Lead Insertion Difficulties, 8 pages

79(SMM) PHO A71463 CAPA 175341 Connector Issue, 4 pages

80(SMM) QSY22465 A71463 NonReportable, 4 pages

81(SMM) CAPA175341 Inability Insert Leads INS, 79 pages

82(SMM) CAPA175341 PR188214, 49 pages

83(SMM) QSY23451 PIA CAPA175341 Inability Insert Leads INS, 18 pages

84(SMM) REG23330 Medical Safety Assessment Neurological Deficit SCS, 50 pages

85(SMM) QSY23403 SCSProcedure Related Neurological Deficit, 8 pages

86(SMM) QSY23403ver4, 15 pages

87(SMM) QMS1799Ver7, 24 pages

88(SMM) QMS1002 Ver 16, 12 pages

89(SMM) REG30552, 17 pages

90(SMM) 2014Complaints Paraylsis, 19 pages

91(SMM) CAPA 176527, 64 pages

92(SMM) Investigation Report for CAPA 176527, 26 pages

93(SMM) PR190039, 4 pages

94(SMM) Reg31093 SCS Device , 9 pages

95(SMM) RSAD9976 MSA Procedure, 9 pages

96(SMM) CAPA 234139, 37 pages

97(SMM) NRP104638520, 29 pages

98(SMM) Investigation Plan for CAPA 234139, 22 pages

99(SMM) QSY27756 Acute Extension Conductor Fractures, 34 pages

100(SMM) BL0021943 Low Ti vs Std Ti MP35N

101(SMM) 163334 Receiving Inspection Procedure , 7 pages

102(SMM) PR255975, 3 pages

103(SMM) Cable Analysis, 6 pages

104(SMM) Reg33372 Labeling Change Request Escalation, 5 pages

105(SMM) QMS1794 TLP Documents Records, 18 pages

106(SMM) DOC9751 Requirements for Quality Records, 18 pages

107(SMM) CAPA168013 PR182625, 5 pages

108(SMM) Recall Log, 1 page

From APPLIED DV SAW 2021-8591 EIR Medtronic Neuromodulation, Minneapolis, MN 12-19-13_Redacted

Establishment Inspection Report FEI: 2182207

EXHIBITS

1. Organizational charts

2. Steering Committee Charter for trial of Specify® 565, 12/20/11, including membership

Records re: DBS for Dystonia:

3. Pre-IDE Package, 10/16/12, including Study Synopsis

4. DRAFT Pre-IDE Meeting Minutes, dated 2/5/13 for meeting 1/14/13

5. protocol, Version 2.0, 4/26/13, including sample Consent Form (section 18.1)

Device labeling:

6. Patient Programmer Pain therapy user manual

7. Medtronic Pain Therapy Information for prescribers (Adverse events summary page 13)

8. Specify® 5-6-5 Implant manual (cautions and warnings page 9)

9. Indications sheet for Medtronic implantable neurostimulation systems

10. Programming sheet

11. Clinical Summary for spinal cord stimulation

12. Clinical Strategy for dated 7/2/12

13. FDA/CDRH approval letter for Specify® 5-6-5 Lead, P840001/S96, 6/11107

14. Portion of Annual Report (29th) for PMA P840001, coverletter dated 11/25/13

15. List of sites

16. Subject listing

17. Annual Study Progress Report, 9/18/13

Disk copies of records regarding:

18. Investigator agreements and IRB approvals

19. Training

20. Correspondence

21 . Monitoring

22. Financi~ Disclosure Decision Tree, 5/8/12

23 nvestigator Meeting Agenda, 1/18-19/13

24. Listing of adverse events

25. Table cross-referencing AEs MDR'd

26. for neuromodulation pain stimulation Charter 7/23/13, including list of members (3 studies)

27. Specify® 565 lead sales, 2007 - 2013

28. Mark-up copy of language to be added to Information to prescribers

29. Neuro Review Form for Product Labeling, with approval signatures as of 12/19/13

30. Letter to FD~ 11/25/13 re: Status Report - Quality Improvement Plan

31. MSA REG 10945, 7/27/11

32. MSA REG 09844, 3/28/11

33. MSI 59129, 10/19/10 - 5/26/11

34. Risk Evaluation Board (REB) Meeting Minutes, 4/7 /11

35. MSA REG 18931, 11/21/13

36. Tier III PIE Board Meeting Minutes, 9/26/13 (doc QSYl 8799, 10/11/13)

37. Product Impact Assessment (PIE), doc QSY18977, 10/3/13

38. CAPA Board (All Boards Neuromodulation) minutes of meeting 11/6/11 (doc CPA20543)

39. CAP A 176174, opened 11/6/13

40. Health Hazard Analysis, initiated 12/9/13

41. CAPA 176527, opened 11/11/13

42. Summary table ofMSAs re: surgical leads (11), including Specify® 5-6-5's

From APPLIED DV SAW 2021-8591 EIR Medtronic Neuromodulation Minneapolis MN 10-17-19_Redacted

Establishment Inspection Report FEI: 2182207

1(SMM) Supported Telemetry Devices with Software Models, 1 page

2(SMM) Internal Audit Plan, 4 pages

3(SMM) QMS1794 TLP Documents, Records and Change Management, 16 pages 4(SMM) Tango Patient and Clinician Instruments, 1 page

5(SMM) Clinician Programmer Software Distn Overview, 2 pages

6(SMM) Mobile Infrastructure App Deployment, 11 pages

7(SMM) A88792 Released Parts Specification Clinician and Patient App software, 4 pages

8(SMM) 019P398 Supplier Segmentation, 12 pages

9(SMM) 10842449DOC Neuro and MPROC Quality Agreement, 40 pages

13(SMM) List of Products, 8 pages

14(SMM) CAPA Process Overview, 7 pages

15(SMM) CAPA Log Since 01012017, 7 pages

16(SMM) SCAPA Log Since 01012017, 2 pages

17(SMM) Field Corrective Action Log since 01012017, 1 page

18(SMM) SCAPA PR 383477 w returned prod pics, 133 pages

19(SMM) PHO A93424, 4 pages

20(SMM) Customer Letter from , 7 pages

21(SMM) Field Action Plan 1902 Curved Tip Introducer Needle, 35 pages

22(SMM) CAPA 165164, 52 pages

23(SMM) Change Control Plan DBS Icefall Leads and Extensions, 34 pages

24(SMM) QSY47415 PIA DBS Lead Depth Stop Not Adequately Holding Lead, 42 pages

25(SMM) Product Hold Order A83018, 2 pages

26(SMM) Change order CO10210792, 7 pages

27(SMM) FA17 11 Field Action Plan DBS Lead Depth Stop, 44 pages

28(SMM) Multisource quotes and POs, 8 pages

29(SMM) SCQ35483 ECO 3849, 10 pages

30(SMM) SUPD1742, 24 pages

31(SMM) SCQ 35475 ECOS, 53 pages

32(SMM) CPA58243 Letters , 3 pages

33(SMM) QSY54602 PIA Depth Stop Design Change Implementation, 20 pages 34(SMM) PHO A92213, 2 pages

35(SMM) CAPA PR382562 , 64 pages

36(SMM) Investigation Is ISNOT Chart, 4 pages

37(SMM) SUPD1337 SCAPA Procedure V25, 16 pages

38(SMM) SUPD1337 SCAPA Procedure V26, 16 pages

39(SMM) SUPD1337 SCAPA Procedure V27, 21 pages

40(SMM) SUPD1337 SCAPA Procedure V28, 23 pages

41(SMM) SUPD1337 SCAPA Procedure V29, 25 pages

42(SMM) SUPD1337 SCAPA Procedure V30, 26 pages

43(SMM) SUPD1337 SCAPA Procedure V31, 27 pages

44(SMM) SUPD1337 SCAPA Procedure V32, 27 pages

45(SMM) SCAPA , 5 pages

46(SMM) SCAPA 421046 Audit Trail Report, 149 pages

47(SMM) SCAPA PR 404494, 54 pages

48(SMM) PVR568 Validation Report, 10 pages

549(SMM) SCAPA PR 381925, 17 pages

50(SMM) SCAPA PR 52534, 20 pages

51(SMM) SCAPA PR 452534 Audit Trail Report, 62 pages

52(SMM) SCAPA 446673 Audit Trail Report, 27 pages

53(SMM) SCAPA 381925 Audit Trail Report, 205 pages

54(SMM) SCAPA 383477 Audit Trail Report, 401 pages

55(SMM) DOC1010 Quality System Documents, 19 pages

56(JDG) E056 Lists of Medtronic Neuro Products, 8 pages

57(JDG) E057 3A List of Shipped non infusion products with submission info , 17 pages

58(JDG) E058 Organization Charts for RTG and Pain Therapies 14 pgs, 14 pages

59(JDG) E059 12 Log Employee Name Title Responsibilities and Manager FDA 09OCT2019 3 pgs, 3 pages 60(JDG) E060 206 Design Control Story board, 1 page

61(JDG) E061 11 Complaint Handling 027-P043, 8 pages

62(JDG) E062 10 Complaint Handling Process 5 pages

63(JDG) E063 51A NDHF1515-183202 V4.0 FA19-05 Field Action Plan InterStim Therapy Programmer Compatibility, 35 pages

64(JDG) E064 51B CAPA 437803 Full Detail Report, 31 pages

65(JDG) E065 51C QSY64260 V3.0 Product Impact Assessment for Tango Clinician App A510 Amplitude Jump to Unexpected Value, 16 pages

66(JDG) E066 51D NDHF1515-183575 V2.0 Risk Assessment Summary in Support of Field Action FA19-05, 7 pages

67(JDG) E067 134A Complaint PE 702957006 , 14 pages

68(JDG) E068 134B Complaint PE 702972514, 15 pages

69(JDG) E069 134C Complaint PE 702994984, 14 pages

70(JDG) E070 134D Complaint PE 702994993, 15 pages

71(JDG) E071 134E Complaint PE 702996926 , 15 pages

72(JDG) E072 134F Complaint PE 703005637 13 pgs, 13 pages

73(JDG) E073 134G Complaint PE 703018046, 13 pages

74(JDG) E074 134H Complaint PE 703041361, 8 pages

75(JDG) E075 134I Complaint PE 703041760, 18 pages

76(JDG) E076 134J Complaint PE 702995146, 14 pages

77(JDG) E077 176 Complaint PE 703115606, 16 pages

78(JDG) E078 177 Complaint PE 703148180, 23 pages

79(JDG) E079 178 Complaint PE 703203273, 10 pages

80(JDG) E080 179 Complaint PE 703264446, 16 pages

81(JDG) E081 198 Complaint PE 703225772, 20 pages

82(JDG) E082 132 NC PR 432233, 15 pages

83(JDG) E083 435 NDHF1515-156791_v11.0, 14 pages

84(JDG) E084 334 NDHF1515-156791 Version 12.0 - Tango Hazard Analysis , 26 pages

85(JDG) E085 332 NDHF1515-156791 Version 14.0 - Tango Hazard Analysis, 27 pages

86(JDG) E086 335 Change Request 309627, 11 pages

87(JDG) E087 372B NDHF1515-139891_v15.0, 43 pages

88(JDG) E088 135 NDHF1515-139891 V16.0 Tango Design Plan, 41 pages

89(JDG) E089 372A _v14.0 Design Input Requirements, 10 pages

90(JDG) E090 205 V17 Desigin Input Requirements , 12 pages

91(JDG) E091 401B QMS32712_v7 Product Risk Management, 26 pages

92(JDG) E092 184 NDHF1515-141105 Risk Management Plan for Tango Therapy Application Software V6.0, 12 pages

93(JDG) E093 401A QMS32712_v9 Product Risk Management, 28 pages

94(JDG) E094 437 QMSWI33002 Ver. 4.0 Hazard Analysis, 17 pages

95(JDG) E095 344 QMSWI33002 V6 Hazard Analysis, 22 pages

96(JDG) E096 136 NDHF1522-147078 V7.0 Tango TAS Reqs Traceability and Critical Software Requirements Rationale, 89 pages

97(JDG) E097 276 NDHF1522-167208_Trace, 42 pages

98(JDG) E098 328 Adjust Therapy Ampitude Test report (AT-54715), 3 pages

99(JDG) E099 277 NDHF1522-169432 Tango Software Verification Report (Release 2.0) , 188 pages

100(JDG) E0100 182 NDHF1522-142167_v12.0 Tango App Software Development and Verification Plan , 32 pages

101(JDG) E0101 302 NDHF1515-157984 V4 SNM Clinician and Patient Application Intended Use and User Needs Document, 5 pages

102(JDG) E0102 279 NDHF1515-164784 V6 Tango Clinician and Patient Application Requirements Trace Report, 49 pages

103(JDG) E0103 295 NDHF1515-163108 V4 SNM Clinician and Patient App System Design Validation Plan, 10 pages

104(JDG) E0104 293 NDHF1515-170860 V4 SNM Clinician and Patient App Systems Design Validation Summary, 12 pages

105(JDG) E0105 451 NDHF1515-169918 Ver. 2.0 SNM Clinician and Patient Application System Design Verification Report 1, 43 pages

106(JDG) E0106 453 NDHF1515-170669 Ver. 3.0 SNM Clinician and Patient App System Design Val Analytical and Rationale, 26 pages

107(JDG) E0107 183 NDHF1515-164710_v5.0 SNM Clinician and Patient Application System Requirements, 30 pages

108(JDG) E0108 307 Manage Therapy Programming Test (AT-67553), 2 pages

109(JDG) E0109 371 NDHF1515-140837 V7 Business Plan, 40 pages

110(JDG) E0110 201 UC201809408EN SNM InterStim Smart Programmer eLearning FY19, 106 pages

111(JDG) E0111 231 Programing Guide M974675A_a_001_view_color, 60 pages

112(JDG) E0112 318A M974740A_a_001, 48 pages

113(JDG) E0113 318B Clinician Brochure V2_ UC201903048bEN, 15 pages

114(JDG) E0114 339A InterStim Smart Programmer Launch Kit, 4 pages

115(JDG) E0115 339B Therapy Pocket Guide, 11 pages

116(JDG) E0116 339D InterStim Smart Programmer Technology and Resource Guide, 8 pages

117(JDG) E0117 420A TRN 35109_v11.0 QST-NEU-513825 IL Design Input Reqs Practitioner 46 pages

118(JDG) E0118 420B _v6.7_DRAFT Usability Engineering, 11 pages

119(JDG) E0119 420C _v4.22_DRAFT Development of Health Software Products, 48 pages

120(JDG) E0120 421 TRN 70103_ V2 CAPA 437803 Compatability Requirements Training, 12 pages 121(JDG) E0121 107 PHO A97774, 3 pages

122(JDG) E0122 137 NCR65392 V2 Product Nonconformance Record for QSY64260, 4 pages

123(JDG) E0123 245B Defect DFCT-626803 Amplitude Jump to default upper amplitude limit (Tango MRC), 2 pages

124(JDG) E0124 199 NDHF1567-183660 Tango MRC Programmer Interchangeability Integration Report V2.0, 58 pages

125(JDG) E0125 224 Defect DFCT-646633 Amplitude Limit Set to 0.0 , 2 pages

126(JDG) E0126 245A NDHF1577-185640 V2 Tango MRC Software Release Report, 44 pages

127(JDG) E0127 232 for and 4 Firmware and Software, 3 pages (4)

128(JDG) E0128 259 Anomaly Dispostion (AD) 310376_Completed, 25 pages 129(JDG) E0129 Electronic Copy of electronic records, 2 pages

130(JDG) E0130 Electronic Working Copy of Electronic records 1 pg, 1 page

We have tried to be as comprehensive as possible to name all of the exhibits within the amended request. As far as we can tell, all of these documents are in your possession. Our position is that the large majority of these documents are not subject to any exemptions. We reserve our rights to challenge any exemptions.

How much more time do you need to get us these records. Demand is formerly made upon you for an estimated

If you have any questions about handling this request, you may message me at EbanVF40@gmail.com.

Sincerely,

Katherine Eban
623 11th St.
Brooklyn, NY 11215
EbanVF40@gmail.com

Gmail

Katherine Eban <ebanvf40@gmail.com>

FDA Amended FOIA Response 2021-8591

Williams, Sandra A <SandraA.Williams@fda.hhs.gov> Tue, May 3, 2022 at 8:13 AM
To: Katherine Eban <ebanvf40@gmail.com>

Good morning

Thanks for your email. I have forwarded your May 1, 2022 letter to the Division of FOIA for logging as a new FOIA request. For any future requests for exhibits or attachments associated with any previous requests please use the FDA.GOV FOIA request portal for submitting requests.

Thank you,

Sandra Williams

Government Information Specialist

Food and Drug Administration

Division of Information Disclosure Policy

FOIA Branch East

Sandraa.Williams@fda.hhs.gov

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