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**BRIEF DESCRIPTION OF REPRESENTATIVE SIGNIFICANT ACTIVITIES DURING THE  
REGULATORY PERIOD FOR CHANTIX™ (varenicline) Tablets**

Date	Activity	Comments
14-Sep-99	Submission to FDA	Initial IND
20-Sep-99	Correspondence from FDA	Initial IND acknowledgement
22-Sep-99	Response to FDA	Response to 20-Sep-99 request for IND desk copies
13-Oct-99	Submission to FDA	Clinical
22-Oct-99	Submission to FDA	Change in Protocol
26-Jan-00	Submission to FDA	New Protocol; CMC
23-Feb-00	Submission to FDA	New Investigator; Revised FDA-1572 Form
9-Mar-00	Response to FDA	Response to FDA 1&2-May request for pk protocol and safety tables
31-Mar-00	Response to FDA	Response to FDA Request for Information; clinical agreements 21-Mar-00
5-Apr-00	Correspondence from FDA	Minutes of Phase 2 Study Protocol 1002 telecon
19-Apr-00	Response to FDA	Response to FDA 21-Mar-00 Request, Amendment to Study Protocol 1002
22-May-00	Submission to FDA	New Investigator
22-May-00	Correspondence from FDA	Comments on Phase 2 Study Protocol 1002 amendment
25-May-00	Submission to FDA	Clinical
8-Jun-00	Submission to FDA	CMC
27-Jun-00	Submission to FDA	Safety Report
29-Jun-00	Submission to FDA	New Investigator
14-Jul-00	Submission to FDA	New Protocol; New Investigator
21-Jul-00	Submission to FDA	New Investigators; CMC
18-Aug-00	Submission to FDA	New Investigator
6-Sep-00	Submission to FDA	Investigator's Brochure
29-Sep-00	Submission to FDA	Protocol Amendment; New Investigator; Toxicology
6-Oct-00	Submission to FDA	IND Annual Report
26-Oct-00	Submission to FDA	New Protocol; New Investigator; CMC
1-Nov-00	Submission to FDA	New Protocol; New Investigator; CMC
6-Dec-00	Correspondence from FDA	Recommendation for smoking status in Study 1006
12-Dec-00	Submission to FDA	Revised FDA 1572 Forms; Toxicology
9-Jan-01	Submission to FDA	Amendment to Study Protocol 1006
7-Mar-01	Submission to FDA	Revised FDA 1572 Forms; CMC
13-Mar-01	Response to FDA	Response to FDA re Study 1006 smoking status telecons 7Dec2000&22Feb2001
22-Mar-01	Submission to FDA	Revised FDA 1572 Form
6-Apr-01	Correspondence from FDA	Preclinical questions on initial IND
9-Apr-01	Submission to FDA	Toxicology
30-May-01	Submission to FDA	New Protocol, New Investigator, Chemistry, Manufacturing & Controls
7-Jun-01	Submission to FDA	Change in Protocol; Revised FDA-1572 Form
8-Jun-01	Response to FDA	FDA on review of IND and Phase 2 Program. Responses 31-Mar-00, 1-Apr-00, 25-May-00
28-Jun-01	Submission to FDA	General Correspondence: Request for Meeting to discuss Study 1002 results
16-Jul-01	Submission to FDA	New Protocol; New Investigator; Clinician's CV; Revised FDA-1572 Forms
23-Jul-01	Correspondence from FDA	Date for Type C meeting Sept 5 2001
17-Aug-01	Submission to FDA	General Correspondence: Briefing Package for Sept 5 2001 meeting
24-Aug-01	Submission to FDA	New Investigators; Toxicology
18-Sep-01	Submission to FDA	New Protocol; New Investigator; CMC

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26-Sep-01	Correspondence from FDA	Minutes of Type C meeting Sept 5 2002
27-Sep-01	Submission to FDA	New Protocol; New Investigator; CMC
18-Oct-01	Submission to FDA	IND Annual Report
18-Oct-01	Submission to FDA	New Investigator; CMC
29-Oct-01	Submission to FDA	New Protocol; New Investigator
5-Nov-01	Submission to FDA	New Protocol; New Investigator
16-Nov-01	Submission to FDA	Meeting Minutes from 5Sept2001; New Protocol; Revised FDA-1572 Forms; CMC
20-Nov-01	Submission to FDA	New Investigators; Revised FDA 1572 Form
14-Dec-01	Submission to FDA	New Investigator; Investigator Brochure
20-Dec-01	Submission to FDA	New Protocol; New Investigator
21-Dec-01	Submission to FDA	Information amendment, Clinical
10-Jan-02	Submission to FDA	Change in Protocols; New Investigators
11-Feb-02	Submission to FDA	New Investigators
8-Mar-02	Submission to FDA	Protocol, CMC
14-Mar-02	Submission to FDA	New Protocol, Protocol Change
19-Mar-02	Submission to FDA	Change in Protocols; New Investigators
2-Apr-02	Submission to FDA	Change in Protocols; New Investigators
8-Apr-02	Submission to FDA	New Protocol; New Investigators
25-Apr-02	Submission to FDA	New Investigator; Revised FDA-1572 Forms; CMC
25-Apr-02	Submission to FDA	Protocol Change
29-Apr-02	Submission to FDA	Toxicology
2-May-02	Submission to FDA	Request for Special Protocol Assessment
7-May-02	Submission to FDA	Request for Special Protocol Assessment
22-May-02	Submission to FDA	New Investigators; Revised FDA-1572 Forms; Toxicology
5-Jun-02	Response to FDA	Response to FDA request for information 3-Jun-02, Toxicology
13-Jun-02	Correspondence from FDA	Further CAC recommendations
26-Jun-02	Submission to FDA	New Investigators, Revised FDA 1572 Forms
3-Jul-02	Submission to FDA	Request for Special Protocol Assessment, Info Amendment - Pharm/Tox
11-Jul-02	Response to FDA	9-Jul-02 FDA request for information, Pharmacology
16-Jul-02	Submission to FDA	Revised FDA 1572 Forms; Update IB
2-Aug-02	Correspondence from FDA	CAC recommendations
16-Aug-02	Submission to FDA	New Investigator, Revised FDA 1572 Forms
28-Aug-02	Submission to FDA	Protocol, New Investigator, CMC, Labels, Investigator CV
6-Sep-02	Submission to FDA	New Investigator, CMC
12-Sep-02	Submission to FDA	General Correspondence: EOP2 Meeting Request
1-Oct-02	Submission to FDA	CMC, Toxicology
4-Oct-02	Submission to FDA	New Investigator, Revised FDA 1572 Forms
21-Oct-02	Correspondence from FDA	Date for End of Phase 2 meeting
29-Oct-02	Submission to FDA	IND Annual Report
7-Nov-02	Submission to FDA	End of Phase 2 Meeting Package
8-Nov-02	Submission to FDA	Investigator's Brochure
15-Nov-02	Submission to FDA	New Protocol; Revised FDA 1572 Form; CMC
27-Nov-02	Response to FDA	Response to FDA Questions 26-Nov-02 Quit rates

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17-Dec-02	Submission to FDA	Minutes: End-of-Phase 2 Meeting
17-Dec-02	Submission to FDA	New Investigators; CMC
3-Jan-03	Submission to FDA	General Correspondence: Response to FDA's 31Dec2002 recommendation for Study 1024
6-Feb-03	Correspondence from FDA	Minutes of End of Phase 2 meeting
6-Feb-03	Submission to FDA	Revised FDA 1572 Forms, General Correspondence: USAN Name
7-Feb-03	Submission to FDA	New Protocol Study 1035
7-Mar-03	Submission to FDA	New Investigator, January 2003 Erratum, New contact
19-Mar-03	Submission to FDA	Change in Protocol Study 1024; New Investigator
10-Apr-03	Submission to FDA	Revised FDA 1572 Form; CMC
9-May-03	Submission to FDA	Change in Protocol Study 1035; New Investigator; Revised FDA 1572 Form
3-Jun-03	Submission to FDA	Change in Protocols Studies 1018 and 1019; New Investigator; Revised FDA 1572 Form
9-Jun-03	Submission to FDA	New Protocol Study 1028, New Investigator, CMC
26-Jun-03	Submission to FDA	New Protocol Study 1036; New Investigator; Revised FDA 1572 Forms
1-Jul-03	Submission to FDA	Revised FDA 1572 Form
11-Jul-03	Submission to FDA	New Investigators
16-Jul-03	Submission to FDA	New Protocol Study 1031; New Investigator
13-Aug-03	Submission to FDA	New Investigators; Revised FDA 1572 Forms
15-Aug-03	Submission to FDA	General Correspondence Request for Meeting CMC/EOP2
21-Aug-03	Correspondence from FDA	Comments on inclusion criteria in 1028 and 1036
27-Aug-03	Submission to FDA	New Investigators, Revised FDA 1572 Forms; CMC
27-Aug-03	Submission to FDA	General Correspondence: Request for Meeting (CMC)
28-Aug-03	Response to FDA	General Correspondence - Response to Request for Information
4-Sep-03	Correspondence from FDA	Date and details for EOP2 (CMC) meeting
10-Sep-03	Submission to FDA	End of Phase 2 CMC Meeting Information: Pre-meeting Information Package for CMC
18-Sep-03	Submission to FDA	Protocol Amendments for studies 1028 & 1036, New Investigators, Revised FDA 1572
25-Sep-03	Submission to FDA	New Protocols, New Investigators
10-Oct-03	Submission to FDA	New Protocols, New Investigators, CMC
20-Oct-03	Submission to FDA	New Protocol; New Investigator
5-Nov-03	Submission to FDA	New Investigators; Revised FDA 1572 Forms; CMC
7-Nov-03	Submission to FDA	New Protocol; New Investigator
11-Nov-03	Correspondence from FDA	FDA EOP2 (CMC) minutes
13-Nov-03	Submission to FDA	IND Annual Report
2-Dec-03	Submission to FDA	New Investigators, Revised FDA 1572 Forms
9-Dec-03	Submission to FDA	Investigator's Brochure
22-Dec-03	Submission to FDA	General Correspondence: EOP2 meeting minutes clarification; abuse liability briefing
15-Jan-04	Submission to FDA	New Investigators, Revised FDA 1572 Forms
13-Feb-04	Submission to FDA	Safety Letter
10-Mar-04	Submission to FDA	New Investigators, Revised FDA 1572 Forms, IB Addendum
22-Mar-04	Correspondence from FDA	Request for additional information re abuse potential briefing document
23-Mar-04	Submission to FDA	Information Amendment CMC
30-Mar-04	Submission to FDA	Pharmacology/Toxicology
7-Apr-04	Submission to FDA	Safety Report
13-Apr-04	Submission to FDA	Response to abuse potential questions, New Investigator, Revised FDA 1572 Forms

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3-May-04	Submission to FDA	CMC; Revised FDA 1572 Forms
12-May-04	Submission to FDA	Safety Report
21-May-04	Submission to FDA	General Correspondence - Clinical; request for feedback on P3 narratives proposal
26-May-04	Submission to FDA	CMC
1-Jun-04	Submission to FDA	Safety Letter
22-Jun-04	Submission to FDA	Revised FDA 1572 Forms
14-Jul-04	Submission to FDA	Meeting Request to discuss CMC related NDA filing strategies
6-Aug-04	Submission to FDA	Revised FDA 1572 Forms
23-Aug-04	Submission to FDA	Safety Letter
31-Aug-04	Submission to FDA	Safety Letter
13-Sep-04	Submission to FDA	Pre meeting Information Package for CMC
21-Sep-04	Submission to FDA	New Protocol, New Investigator
28-Sep-04	Submission to FDA	New Protocols, New Investigators, CMC
19-Oct-04	Submission to FDA	IND Annual Report
20-Oct-04	Submission to FDA	General Correspondence: Tradename proposal
2-Nov-04	Submission to FDA	Toxicology, Clinical Study Report, Revised FDA 1572 Forms
5-Nov-04	Submission to FDA	Follow up Safety Letter
10-Nov-04	Response to FDA	General Correspondence: Summary of Agreements from Type C CMC Meeting
9-Dec-04	Submission to FDA	New Protocol, New Investigator, CMC, Revised FDA 1572 Forms
21-Dec-04	Correspondence from FDA	Meeting Minutes 14Oct04
22-Dec-04	Response to FDA	responses to issues raised in 13Apr04 assessment of amendment dated 13apr04 re
6-Jan-05	Submission to FDA	New Investigator, New Protocol
21-Jan-05	Response to FDA	Comments on FDA meeting minutes re comparability protocols from 14Oct04 CMC
4-Feb-05	Submission to FDA	Toxicology reports, Protocol Amendment, New Protocol, New Investigator, Revised FDA
11-Feb-05	Submission to FDA	Clinical, CMC
25-Feb-05	Submission to FDA	Request for a pre-NDA meeting
11-Mar-05	Submission to FDA	New Investigator, CMC
23-Mar-05	Correspondence from FDA	Letter confirming date of Pre-NDA meeting
1-Apr-05	Submission to FDA	Safety Letter
5-Apr-05	Submission to FDA	Protocol Amendment - New Investigators; Revised FDA 1572 Form
18-Apr-05	Submission to FDA	Comparability Protocol
22-Apr-05	Submission to FDA	Information amendment: Statistical analysis plan
22-Apr-05	Submission to FDA	Information Amendment Clinical
5-May-05	Submission to FDA	New Investigators, Revised FDA 1572 Forms
6-May-05	Submission to FDA	General Correspondence statistical analysis plan for Study 1039
10-May-05	Submission to FDA	Briefing Document for Pre-NDA meeting
11-May-05	Response to FDA	Response to FDA questions related to Statistical Analysis Plan
17-May-05	Submission to FDA	New Protocol, New Investigator, CMC, Revised FDA 1572 Forms
27-May-05	Submission to FDA	Safety Letter
20-Jun-05	Response to FDA	Response to FDA Request for Information from the Pre-NDA meeting
22-Jun-05	Submission to FDA	New Investigator, CMC, Revised FDA 1572 Forms
30-Jun-05	Submission to FDA	Comparability Protocol
3-Aug-05	Submission to FDA	Proposed Comprehensive Quality Overview Summary for the Varenicline Tartrate NDA

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3-Aug-05	Submission to FDA	Protocol Change
23-Sep-05	Submission to FDA	General Correspondence -PRO document
4-Oct-05	Submission to FDA	General Correspondence: Request for meeting with Office of New Drug Chemistry
11-Oct-05	Submission to FDA	New Protocol, CMC, Revised FDA 1572 Forms
24-Oct-05	Submission to FDA	General Correspondence: Feedback on FDA minutes from 18 Aug 2005 Abuse Liability
9-Nov-05	Submission to FDA	New Drug Application
21-Nov-05	Submission to FDA	General Correspondence: NDA Safety Update Proposal
2-Dec-05	Submission to FDA	Annual Report
8-Dec-05	Submission to FDA	New Protocols; CMC
6-Jan-06	Correspondence from FDA	Meeting minutes from 9Jun05 Pre-NDA meeting
13-Jan-06	Submission to FDA	Type C Meeting Request
27-Jan-06	Submission to FDA	New Investigators, Revised FDA 1572 Forms, Clinical
3-Feb-06	Response to FDA	FDA Query received 25Jan06 related to report links and study locations
7-Feb-06	Submission to FDA	Stability Update
9-Feb-06	Submission to FDA	3 mo Safety Update
13-Feb-06	Response to FDA	FDA Query received 27Jan06 related to Qualifying Procedures and report datasets
3-Mar-06	Response to FDA	FDA request received 28Feb06 for reconciliation and data
3-Mar-06	Submission to FDA	Request for pre-approval importation
10-Mar-06	Submission to FDA	New protocol, New Investigators and Revised FDA 1572 Forms
8-Mar-06	Response to FDA	FDA request received 6Mar06 for updated CTD sections
10-Mar-06	Response to FDA	FDA request received 3Mar06 for histories and measures tables
14-Mar-06	Response to FDA	FDA letter received 6Mar06 regarding Trade Name
14-Mar-06	Response to FDA	FDA request received 3Mar06 dependence
14-Mar-06	Response to FDA	FDA request received 7Mar06 for AE tables
15-Mar-06	Response to FDA	FDA request received 10Mar06 for QT data
23-Mar-06	Response to FDA	FDA request received 20Mar06 SAEs
24-Mar-06	Response to FDA	FDA request received 21Mar06 for different presentation of table
27-Mar-06	Response to FDA	FDA request received 23Mar06 for data
29-Mar-06	Response to FDA	FDA Query received 20Mar06 related to interpretation of CPK values
31-Mar-06	Response to FDA	FDA request received 27Mar06 for new AE data
31-Mar-06	Response to FDA	FDA request received 30Mar06 for data
7-Apr-06	Response to FDA	FDA request received 31Mar06 for data tables
11-Apr-06	Response to FDA	Quality Queries
20-Apr-06	Response to FDA	Quality Queries Received 24Feb and 13Mar06
1-May-06	Response to FDA	Follow to 27Apr06 telecon related to dosing
4-May-06	Response to FDA	Quality Queries 21April and May4,06
9-May-06	Response to FDA	Quality Queries 05May06
10-May-06	Correspondence from FDA	FDA letter received May 5 and telecon May 9 regarding package label
11-May-06	Submission to FDA	Final Printed Label and Promotional Materials