

# **Exhibit C**

**Product: MultiHance® (gadobenate dimeglumine injection)**

**IND # 43,779**

**IND FDA Correspondence**

<b><u>Date</u></b>	<b><u>Ser. No.</u></b>	<b><u>Description</u></b>
<b>Volume 2.0</b>		
10/23/93	000	Submission of Original IND
11/1/93		FDA Acknowledgement of receipt of IND
11/12/93		Submission of protocols on diskette (Response to 11/9/93 request)
11/16/93		Request from Dr. Dunn for CMC info.
11/22/93	001	CMC Response to 11/16/93 request for Info.
11/24/93		First notification of Clinical Hold From FDA
2/10/94		Letter from FDA with clinical hold issues.
3/8/94		<b>Questions/Concerns re: clinical hold comments for discussion in proposed teleconference</b>
3/18/94		<b>Fax with response to Question 1a Safety for discussion in teleconference</b>
3/22/94		Fax From FDA with Pharmacologist's comments/requests
4/18/94		FDA Request for information/questions/arguments in advance of May 4, 1994 meeting with Drs. Pierro & Jones
5/4/94		FDA Meeting
5/13/94	005	Submission of reanalyzed Phase II data as requested in 2/10/94 letter.
5/16/94		FDA Clarification of Cardiac Toxicity Issues
5/17/94	006	Submission of Response to Chemistry issues in 2/10/94 letter
5/27/94	007	Submission of minutes from May 4, 1994 Meeting
5/31/94		FDA Request for conclusion/summary to the statistical report for the reanalyzed Phase II data submitted
6/3/94	008	Submission of Response to Safety/Clinical issues in 2/10/94 letter.
6/10/94	009	Submission of Summary and Conclusion of Statistical Report for the reanalyzed Phase II data requested on 5/31/94
7/6/94	010	submission of additional Phase II clinical data not provided in original IND and Submission of Protocol 021
7/12/94		Phone conversation with FDA reporting release from clinical hold
7/19/94	011	Letter confirming release from clinical hold as indicated in phone conversation on 7/12/94

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7/25/94		FDA Clinical comments to Ser No.-008 (hold response) sent by fax
8/19/94	<b>012</b>	Submission of Protocols 030, 031, and 032 with 1572 and CV for Investigators
8/30/94		FDA Comments on <b>Protocol 021</b> submitted on 7/6/94
9/26/94		Draft FDA Statistical comments on Protocols 030, 031, and 032 sent by Fax
11/1/94	<b>013</b>	Amendment to provide revised 1572s for Investigators in Protocol 015 and Protocol 019
11/1/94		First clinical trial done pursuant to IND, B19036/05, commences
12/21/94	<b>014</b>	IND Annual Report for period 10/93 - 10/94
2/23/95	<b>014a</b>	Submitted to FDA: Transfer of IND to BDI.
2/23/95	<b>015</b>	Submitted to FDA: Amendment I to Protocol -15.
4/4/95		FDA Fax: Draft Statistical comments, <b>Protocol B19036/15 Amend I</b>
4/14/95		FDA Fax: Draft Clinical Comments, <b>Protocol B19036/15 Amend I</b>
7/6/95		FDA Request for clarification of test subjects for iron metabolism and urine metals and gadolinium, dated 7/6/95. (Conf. 2/10/94 FDA Letter)
7/18/95		Tele-Response to our request (7/6/95) for clarification from FDA
7/27/95		Official Letter From FDA Removing Clinical Hold after Verbal Notification on July 12, 1994
10/5/95	<b>016</b>	Submitted to FDA: <b>Protocol 19036/015 Amendment 2</b> - provides for increase patient enrollment
2/8/96	<b>018</b>	Annual Report for 10/94-9/95
3/1/96	<b>019</b>	Submission of Protocol 43,779-4 to FDA.
3/16/96	<b>020</b>	Submission of New Investigator Information for Protocol 43779-4
4/8/96		FDA Contact - Facsimile with Comments on Protocol 43,779-4
4/25/96	<b>021</b>	Submission of Protocol 43,779-8
5/15/96	<b>022</b>	Submission of Protocol 43,779-1 With Amend. 1
6/27/96	<b>023</b>	Submission of Amendment No. 1 to Protocol 43,779-8 and New Investigator Information for Protocol 43,779-1
7/30/96	<b>024</b>	Submission of New Investigator Information for Protocol 43,779-1

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<b><u>Date</u></b>	<b><u>Ser. No.</u></b>	<b><u>Description</u></b>
9/3/96		Fax from FDA with draft comments on Protocols 43,779-1 and 43,779-8
10/3/96	<b>025</b>	Submission of Updated Subinvestigator Information
10/11/96	<b>026</b>	Submission of CMC Informational Amendment Process revision, Geneva as alternate site, and new stopper
10/16/96	<b>027</b>	Submission of responses to FDA's Draft Comments on Protocol 43,779-4
11/7/96	<b>028</b>	Submission of Amendment II and New Subinvestigator Information for Protocol 43,779-1
11/25/96	<b>030</b>	Submission of 1996 IND Annual Status Report
11/25/96	<b>031</b>	Submission of Protocol 43779-5
12/12/96	<b>033</b>	Submission of Protocols 43779-9A and 43779-9B with Investigator Information with Rationale for No 72-Hour Follow-Up and Response to August 1994 FDA Comments
1/14/97	<b>034</b>	Submission of Protocol 43779-9A Amendment 1, Protocol 43779-9B Amendment 1, New Investigators
1/30/97	<b>035</b>	Submission of Responses to FDA Draft Comments on Protocols 43779-8 and 43779-1
2/10/97	<b>036</b>	Submission of Pharmacology/Toxicology Information Amendment (Preclinical Study Reports)
2/19/97	<b>037</b>	Submission of New Investigator Information for Protocol 43779-9A, Protocol 43779-5, and 43779-1
3/13/97	<b>038</b>	Submission of New Investigator Information for Protocols 43779-9A and 43779-9B
3/20/97		Draft FDA Statistical Comments on Protocols 43779-9A and 43779-9B
4/24/97	<b>041</b>	Responses to FDA Draft Statistical and Clinical Comments on Protocol B19036/015 Amendment 1
4/25/97	<b>042</b>	Submission of Protocol 43779-6
4/29/97		T-con with FDA to discuss Protocols 43,779 9A and B
5/2/97	<b>043</b>	Submission of New Investigator Information Protocol 43779-9A and Protocol 43779-9B
5/2/97	<b>044</b>	Submission of Request for Teleconference to Discuss Use of Principal Investigator for one study for Blinded Readers in another study
5/6/97		FDA fax requesting literature reference cited in Pharm/Tox reports submitted to the IND in February, 1997
5/16/97	<b>045</b>	Submission of Journal Articles Requested by FDA Pharmacology/Toxicology Reviewer in May 6, 1997 Fax

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5/20/97		FDA t-con
6/3/97	046	Submission of Amendment 2 for Protocols 43779-9A and 43779-9B, New Investigator Information for Protocol 43779-9B, and Amendment 3 for Protocol B19036/015
6/12/97		Fax from FDA with Draft Clinical Comments on Protocol 43779-6
7/8/97		Fax from FDA Draft Comments on Protocols 43779-9A and 43779-9B Amendment 2 and on Protocol B19036/015 Amendment 3
7/9/97	047	Submission of New Investigator Information for Protocol 43779-9A
7/21/97	048	Submission of Response to FDA's Comments on Protocol 43779-6
8/15/97	049	Submission of New/Revised Investigator Information for Protocol 43779-9A, Protocol 43779-9B and Protocol 43779-1
8/21/97	050	Submission of Minutes from April 29, 1997 Teleconference with FDA on Protocols 43779-9A and 43779-9B. Responses to Draft FDA Statistical Comments (faxed March 20, 1997), and Proposals Resulting from the T-con Discussions
8/27/97	051	Submission of May 20, 1997 Teleconference Minutes
9/8/97		FDA Minutes of May 20, 1997 Teleconference
10/23/97	052	Submission of New/Revised Investigator Information for Protocol 43779-9A and for Protocol 43779-9B
11/07/97	053	Submission of Response to FDA's Draft Clinical Comments (faxed 7/8/97) on Amendment 2 for Protocols 43779-9A and -9B and Amendment 3 for Protocol B19036/015
11/14/97	054	Submission of Amendment 3 to Protocols 43779-9A and 43779-6, and Revised Investigator Information Protocol 43779-9A
11/24/97	055	Submission of 1997 IND Annual Report
12/16/97	056	Submission of Protocol 10 to the FDA
4/7/98	057:	Submission for updated investigator information for Protocols 9A and 9B
8/14/98	059	Submission of Reports of General Studies and Reproductive Toxicity Studies
10/07/98	060	Submission of nonclinical pharmacology, safety pharmacology, ADME, and toxicity study reports
11/30/98	062	Submission of Annual IND Status Report for 1997-1998
3/22/99	064	Request for Pre-NDA Meeting

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4/14/99	066	Two Preclinical Study Reports (Japan)
5/14/99	068	Pre-NDA Package
6/17/99		Pre-NDA Meeting with FDA
7/13/99		Memo to BDI and FDA Re: Minutes of MultiHance Pre-NDA Meeting June 17, 1999
	069	Follow-up information to the Pre-NDA Meeting
7/16/99	070	Minutes from the Pre-NDA Meeting
10/13 and 10/21/99		t-con with FDA regarding NDA submission
8/13/99		Fax from the FDA – Comments from the pharmacology/toxicology reviewer are based on the Review of the Pre-NDA Meeting package held June 17, 1999.
10/28/99		Summary of items discussed in T-con of 10/13 and 10/21/99 regarding upcoming NDA Submission
12/20/99	071	Annual Report covering period 10/1/98 to 9/30/99
8/7/00		<b>Letter From FDA:</b> FDA Meeting Minutes from 6/17/99 and T-cons of 10/13/99, 10/21/99 to discuss end of Phase III data and presentation of EKG data in the NDA
10/13/00	077	Submitted ECG Monitoring Protocol 43,779-12
11/13/00	078	Submitted Information for December 13, 2000 T-Con to discuss proposed ECG Study
11/17/00		Additional information for December 13, 2000 T-Con to discuss proposed ECG study
12/13/00		FDA t-con to discuss ECG study and statistical issues
12/14/00		<b>Fax From FDA:</b> Medical Officer and Biostatistician Comments to statistical and EKG safety assessment proposals of 11/17/00 and 10/13/00
1/9/01		<b>Fax From FDA:</b> DDMAC regarding promotional material for MultiHance at Radiological Society annual Meeting. (MACMIS #9603)
1/22/01		<b>Letter to FDA:</b> Warren F. Rumble, DDMAC (MACMIS #9603)
2/01/01		<b>Fax and Letter from the FDA:</b> (Warren Rumble) regarding MACMIS #9603 regarding promotional material for MultiHance
2/08/01		<b>Fax From FDA:</b> USER Fees – ID #4097
2/14/01	083	New Protocol ECG 43,779-12, New Investigator Information
6/25/01	092	Amendment provides for alternate site and revised process for the manufacture of BOPTA and Byk Gulden as an alternate drug product manufacturing site

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1/10/02	095	IND Annual Report for Reporting Period of 10/01/99 – 09/30/01, including updated Investigator's Brochure
12/04/02	130	IND Annual Report: Report Period of 10/01/01 – 09/30/02. Amendment to IB dated June 2002 submitted.
11/30/03	150	IND Annual Report: October 1, 2002 – September 30, 2003
12/22/04	173	IND Annual Report (10/1/03 – 09/30/04)