

Exhibit D

Product: MultiHance® (gadobenate dimeglumine injection)
NDA# 21-357/21-358 and 21-522/21-523

NDA Correspondence Log

<u>Date</u>	<u>NDA No.</u>	<u>Description</u>
4/27/01	21-357 & 21-358	New Drug Application for MultiHance. (Two separate NDA's)
5/09/01	21-357/ 21-358	FDA requested information: FDA requested and was provided copy of Volume 1.1 for NDA 21-357 and NDA 21-358 and Investigator Information for pivotal studies to Dr Ju.
5/21/01		T-con with FDA
5/23/01	21-357/ 21-358	Fax to the FDA additional requested information: Summary of T-con on May 21 and list of Bracco attendees
5/29/01	21-357	FDA acknowledgment of MultiHance NDA 21-357
6/12/01		FDA verbal request for information: Study specific information and on-site CRFs for 4 randomly selected patients for the clinical sites selected for inspection
6/22/01	21-357/ 21-358	FDA verbal request for information and response: FDA requested and was provided the complete list of all batches (and Corresponding formulation) utilized in pre-clinical and clinical studies for both NDAs
7/11/01	21-357/ 21-358	FDA requested information: Submitted study specific information and on-site CRFs for 4 randomly selected patients for the clinical sites selected for inspection in response to verbal request of 6/12/01
8/02/01	21-357/ 21-358	Fax from the FDA: Response of medical officer to questions regarding content of 4-month Safety Update
8/03/01	21-357/ 21-358	Fax from the FDA: Information Request: Request regarding the reporting of exposure, adverse events (sample excel tables provided) and clinical studies in Safety Update
8/15/01	21-357/ 21-358	FDA verbal request for information and response: FDA requested and was provided a copy of Dr. Barr's Documentation for Site Inspection Study 43,779-9A, sent to Karen Kondas.
8/21/01	21-357/ 21-358	Letter to the FDA: Answer to site inspector's (Karen Kondas) question regarding randomization procedure at Dr. Barr's site (43,779-9A) and full randomization list.
8/29/01 8/30/01	21-357/ 21-358	FDA requested information: Study specific information and On and Off-site CRFs for 4 patients for clinical sites selected for inspection for Study 43,779-36 (follow up from 7/11/01 submission)
9/7/01		FDA verbal request for information: Dr Ju requested MRI Transmittal Form Data for Studies 43,779-9A, 43,779-9B, B19036/020, B19036/010 (039) and B19036/036
9/13/01	21-357/ 21-358	Four-Month Safety Update for MultiHance

Product: MultiHance® (gadobenate dimeglumine injection)
NDA#s # 21-357/21-358 and 21-522/21-523

NDA Correspondence Log

<u>Date</u>	<u>NDA No.</u>	<u>Description</u>
9/14/01	21-357/ 21-358	FDA requested information: MRI Transmittal Form Data for Studies 43,779-9A, 43,779-9B, B19036/020, B19036/010 (039) and B19036/036 (requested by Dr Ju 9/7/01)
10/28/01	21-357/ 21-358	Fax from the FDA Steve Langille: (micro questions)
12/05/01	21-357/ 21-358	FDA requested information: Response to facsimile dated 10/28/01 from the FDA requesting additional information on the container/closure integrity test and on holding times for the compounded drug product.
1/10/02	21-357/ 21-358	Letter from the FDA: regarding the review of the four clinical studies (43,779-1, 43,779-9A, 43,779-9B, B19036/036) FDA concludes that we adhered to pertinent Federal regulations and/or good clinical investigational practices.
1/17/02	21-357/ 21-358	FDA verbal request for information (Labeling) and response: FDA requested and was provided updated MultiHance Labeling in electronic and hard copy format for both NDAs 21-357 and 21-358
2/25/02	21-357/ 21-358	Meeting with FDA
2/25/02	21-357/ 21-358	Fax from the FDA: Slide of Preclinical Issues from meeting of 2/25/02
2/26/02	21-357/ 21-358	Response to FDA: Bracco response to FDA questions regarding preclinical information as discussed in the meeting of 2/25/02 (fax and letter).
2/26/02	21-357/ 21-358	FDA requested information from 02/25/02 meeting
2/26/02	21-357/ 21-358	FDA: requested additional information from 02/25/02 meeting
2/28/02		T-con with FDA: Discussions with Dr. Love regarding Claims and Dosing Recommendation and supportive information
3/07/02	21-357/ 21-358	Letter to FDA: Summarization of Recent Discussions with FDA
3/08/02	21-357/ 21-358	Letter to FDA: Correspondence regarding the documentation of CAD for study patients in Study 43,779-12,
3/12/02	21-357/ 21-358	Additional Information to FDA in response to discussions with Dr Love on 2/28/02: Changes made to Claims and Dosing Recommendation and supportive information
3/13/02	21-357/ 21-358	Fax from FDA: Reviewer's Draft Comments (Efficacy, Safety, Clinical Safety, Clinical Pharmacology Chemistry) that were generated before major amendment

Product: MultiHance® (gadobenate dimeglumine injection)
NDA# 21-357/21-358 and 21-522/21-523

NDA Correspondence Log

<u>Date</u>	<u>NDA No.</u>	<u>Description</u>
3/25/02	21-357/ 21-358	Additional Information to FDA: Subset analysis of effects of MH on ventricular repolarization in patients on calcium channel blockers in Study 43,779-12 (follow up from 3/8/02 response)
4/08/02	21-357/ 21-358	Response to FDA: Responses to draft pharmacology/toxicology
4/18/02	21-357/ 21-358	Fax from FDA: Clinical comments requesting the prospective imaging sheets used by blinded reader for both the CNS and Liver Trials
4/18/02	21-357/ 21-358	Response to FDA request: Response to clinical comment of 04/18/02
4/23/02	21-357/ 21-358	FDA t-con
5/01/02	21-357/ 21-358	Response to FDA request for additional information from T-con of 04/23/02.
5/14/02	21-357/ 21-358	Fax from FDA: Clinical comment requesting location in submission of a by-patient evaluation of patients with elevated bilirubin and any liver enzymes
5/14/02	21-357/ 21-358	Response to FDA request : Response to clinical comment of 05/14/02
5/15/02	21-357/ 21-358	Fax from FDA: Clinical comment requesting a table showing the number of subjects with abnormal increase in bilirubin and concomitant increase in one or more liver enzymes
5/15/02	21-357/ 21-358	Response to FDA request : Response to clinical comment of 05/15/02
5/20/02	21-357/ 21-358	FDA t-con
5/20/02	21-357/ 21-358	Fax to FDA: To provide information discussed during T-con of 5/20/02
5/21/02	21-357/ 21-358	Letter to FDA: Clarification of wording of indication, dosage, and administration in follow-up to a comment made during T-con of 5/20/02
<p>Note: In the action letter of May 24, 2002, FDA assigned 2 new NDA numbers for the Liver Indication (21-522 and 21-523 [multipak]) because approvable (CNS) and nonapprovable (Liver) action letters can not be issued to the same NDA. The NDA numbers for the CNS Indication remain 21-357 and 21-358 (multipak). The correspondence will continue to be filed in the same log, but will be identified by the NDA number.</p>		
5/24/02	21-357/ 21-358	Letter and Fax from FDA: The application is approvable letter for the CNS indication once safety, efficacy and chemistry issues are addressed.

Product: MultiHance® (gadobenate dimeglumine injection)
NDA# 21-357/21-358 and 21-522/21-523

NDA Correspondence Log

<u>Date</u>	<u>NDA No.</u>	<u>Description</u>
5/24/02	21-522/523	Letter and Fax from FDA: Non-Approvable Action letter for Liver indication
5/28/02	21-357/358 and 21-522/523	Fax to FDA: Acknowledging receipt of facsimiles of Action Letters and request for confirmation that no additional user fees will be required based on the issuance of the two new NDA numbers
5/29/02	21-357/21-358	Letter To FDA: Notification of intent to amend application for MultiHance for CNS indication
5/29/02	21-522/21-523	Letter To FDA: Notification of intent to amend application for MultiHance for Liver indication
5/30/02	21-357/358 and 21-522/523	Record of FDA Telecommunication: Confirmation that there will be no additional user fees incurred with the issuance of the two new NDA numbers for the Liver Indication. Request that responses to actions letters be submitted to NDA 321-357/358 only.
7/1/02	21-357/21-358	Letter to FDA: Request for a Type C to discuss the non-clinical and clinical safety and efficacy concerns in the action letter of 5/24/02.
7/17/02	21-357/21-358	Fax and Letter From FDA: Meeting date and list of FDA attendees for meeting to discuss the clinical and non-clinical issues safety and efficacy concerns in the action letter of 5/24/02; Original Letter From FDA dated 7/16/02
7/30/02	21-357/21-358	Information Package to FDA: Information Package for 8/28/02 Meeting to discuss the clinical and non-clinical issues safety and efficacy concerns
8/28/02	21-357/21-358	FDA Meeting: End of Review
8/28/02	21-357/21-358	Information From FDA: Slides Presented by FDA at End-of Review Meeting of 8/28/02
8/29/02	21-357/21-358	Fax to FDA: Fax of slide presented by Bracco at End-of Review Meeting of 8/28/02
9/10/02	21-357/21-358	General Correspondence – Other: Submission of 4 new Nonclinical Pharm/Tox protocols and request for comments
9/10/02	21-357/21-358	General Correspondence –Other : Submission of new Nonclinical protocol and Request for comments
9/19/02	21-357/21-358	Clinical Action Plan – Response to Comments to Clinical Action Pan and Request for Comments/T-Con:
10/01/02	21-357/21-358	Fax From FDA : Preliminary draft PharmTox comments on cardiovascular safety study and local tolerance study submitted 9/10/02

Product: MultiHance® (gadobenate dimeglumine injection)

NDAs # 21-357/21-358 and 21-522/21-523

NDA Correspondence Log

<u>Date</u>	<u>NDA No.</u>	<u>Description</u>
11/15/02	21-357/ 21-358	Fax From FDA: Draft comments to responses and clinical action plan submitted 9/19/02
11/18/02	21-357/ 21-358	Request for T-con with FDA clinical and statistical personnel to obtain clarification on FDA's comments dated 11/15/02
11/22/02	21-357/ 21-358	Fax From FDA: Meeting Minutes From 8/28/02
12/02/02	21-357/ 21-358	Letter From FDA: scheduling meeting to discuss FDA comments to 9/19/02 submission (clinical action plan). The meeting is scheduled for 12/11/02.
12/11/02	21-357/ 21-358	FDA Meeting: Discuss Clinical Action Plan
1/20/03	21-357/ 21-358	Revised Protocol MH-105 and MH-106 (re-read images for 43,779-9A/B and B19036/020 as an alternate to a new study.
1/23/03	21-357/ 21-358	Fax From FDA: Meeting Minutes From 12/11/02 Meeting to discuss/clarify FDA's comments (to the clinical action plan)
1/29/03		T-con with FDA: to discuss outcome of the Cardio-Renal consult evaluation of study number 43,779-12 (Holter ECG study of effect on cardiac electrophysiology that was submitted with the 4-month safety update on 9/13/01)
2/6/03	21-357/ 21-358	Fax From FDA: Meeting Minutes From 1/29/03 T-Con to provide the sponsor with an update on the Cardio-Renal consult evaluation of study number 43,779-12 (Holter ECG study of effect on cardiac electrophysiology that was submitted with the 4-month safety update on 9/13/01).
2/28/03	21-357/ 21-358	Fax From FDA: Comments to protocols (MH-105 and MH-106)
3/5/03	21-357/ 21-358	Letter to FDA: To thank them for their comments; requesting feedback from cardio-renal division regarding the assessment of QTc prolongation.
3/7/03	21-357/ 21-358	Letter From FDA: Clarification that the comments to the re-read protocols (faxed 2/28/03)
3/10/03	21-357/ 21-358	Letter/Fax From FDA: Discipline Review Letter (Cardio-renal review).
10/10/03	21-357/ 21-358	Response to FDA Action Letter of May 24, 2002
11/19/03	21-357/ 21-358	Fax From FDA: Statistical comments to resubmission dated 10/10/03.
11/25/03	21-357/ 21-358	FDA t-con: To discuss blinded read training

Product: MultiHance® (gadobenate dimeglumine injection)
NDA#s # 21-357/21-358 and 21-522/21-523

NDA Correspondence Log

<u>Date</u>	<u>NDA No.</u>	<u>Description</u>
12/4/03	21-357/ 21-358	Letter From FDA: FDA Acknowledgement of 10/10/03 Resubmission.
12/9/03	21-357/ 21-358	Additional Information for MH-105 (blinded re-read): Lesion Tracking and Data Handling Documentation for blinded re-read study MH-105
12/9/03	21-357/ 21-358	Response to FDA Statistical Comments of 11/19/03
1/12/04	21-357/ 21-358	Verbal request from FDA for electronic labeling
1/12/04	21-357/ 21-358	Fax From FDA: CMC comments to labeling
1/14/04	21-357/ 21-358	FDA t-con: clinical/statistical pre-dose issues
1/16/04	21-357/ 21-358	Response to 1/12/04 Fax. Electronic and paper copies of package insert and vial and carton labels with revised chemical structure.
1/28/04	21-357/ 21-358	FDA t-con: Safety database questions
2/3/04	21-357/ 21-358	Replacement pages for Submission dated 10/10/03
2/6/04	21-357/ 21-358	Response to Request For Information. Stemming from T-con of 1/28/04
2/10/04	21-357/ 21-358	FDA verbal request for debarment/patent update
2/11/04	21-357	Updated Debarment Statement and Patent Information. No additional Patents have been issued.
2/11/04	21-357/ 21-358	Fax From FDA: Pharm/Tox comments regarding injection volume in perivenous study and positive control and PVCs in ECG study
2/12/04	21-357/ 21-358	Fax From FDA: Meeting Minutes from 11/25/03 T-con to clarify blinded reader's training for resubmission dated 10/10/03
2/13/04	21-357/ 21-358	Fax From FDA: Meeting Minutes From T-con of 1/14/04 to clarify distribution of changes from Pre-dose lesions in resubmission
2/17/04	21-357/ 21-358	Response to FDA Pharm/Tox Comments of 2/11/04
2/18/04	21-357/ 21-358	FDA t-con: Indication language/clinical wording in proposed PI

Product: MultiHance® (gadobenate dimeglumine injection)
NDA#s # 21-357/21-358 and 21-522/21-523

NDA Correspondence Log

<u>Date</u>	<u>NDA No.</u>	<u>Description</u>
2/20/04	21-357/ 21-358	Fax From FDA: Meeting Minutes From T-con of 1/28/04 to discuss possible transcription errors in safety database text in 10/10/03 submission as well as safety comparison with other drugs that use same transporter as MultiHance.
2/20/04	21-357/ 21-358	Changes to Dosage and Administration and Adverse Event Sections of the PI (in response to T-con of 2/18/04): Amended statement providing for use of power injector because only safety data was provided
2/25/04	21-357/ 21-358	FDA t-con: AE Events
2/27/04	21-357/ 21-358	Response to Requests from 2/25/04 T-Con (AEs):
3/24/04	21-357/ 21-358	Fax From FDA: Meeting minutes From T-Con of 2/18/04 to clarify number of patients in proposed labeling and addition of power injector statement.
4/14/04	21-357/ 21-358	Fax/Letter From FDA: Action Letter in response to resubmission of 10/10/03. The application is approvable for CNS once efficacy issues have been addressed.
4/1/4/04	21-357/ 21-358	Letter to Dr Houn: Intent to amend application.
4/14/04	21-357/ 21-358	Letter to Dr Mills: Intent to Amend Application and Meeting Request.
4/21/04	21-357/ 21-358	Amended Type A Meeting Request: Propose the week of 5/24/04 as meeting date.
4/28/04	21-357/ 21-358	Amended Type A Meeting Request: Request that the meeting be postponed until week of 6/21/04.
5/5/04	21-357/ 21-358	Amended Type A Meeting Request: Request that the meeting be postponed until week of 7/5/04.
5/7/04	21-357/ 21-358	Letter From FDA: Type A meeting requested on 5/5/04 has been scheduled for 7/9/04
5/13/04	21-357/ 21-358	Meeting Request Information Package for Type A Meeting,
6/10/04	21-357/ 21-358	Information Package for 7/9/04 Meeting to resolved efficacy issues in the Approvable letter of 4/14/04.
7/8/04	21-357/ 21-358	From FDA: Division Responses to Questions to be discussed at July 9 Meeting.
7/9/04	21-357/ 21-358	FDA Meeting: Action letter issues

Product: MultiHance® (gadobenate dimeglumine injection)
NDA#s # 21-357/21-358 and 21-522/21-523

NDA Correspondence Log

<u>Date</u>	<u>NDA No.</u>	<u>Description</u>
7/16/04	21-357/ 21-358	Response to FDA Information Request from July 9, 2004 Meeting.
7/23/04	21-357/ 21-358	From FDA: Follow-up to Meeting of July 9, 2004.
7/30/04	21-357/ 21-358	Response to Letter of July 23, 2004
8/6/04	21-357/ 21-358	From FDA: Meeting Minutes from Meeting of July 9, 2004
8/16 & 8/20/04	21-357/ 21-358	FDA request for/t-con to discuss statistical issues
8/27/04	21-357/ 21-358	Safety Update
9/3/04	21-357/ 21-358	Request For Information: Information on how patients were classified for subset analysis submitted on 7/30/04
9/14/04	21-357/ 21-358	FDA t-con: clarification of information in 9/3/04 submission
9/14/04	21-357/ 21-358	Request for Information: Replacement SAS Transport file (tumor1.xpt)
9/15/04	21-357/ 21-358	Minutes From Sept 14, 2004 T-Con: Purpose of T-con was to clarify the information provided in the 9/3/04 submission (tumor vs nontumor analysis).
10/7/04	21-357/ 21-358	From FDA: Meeting Minutes From Stat T-Con on Aug 20, 2004. Purpose of T-Con was to discuss 7/30/04 submission (tumor vs non-tumor analysis)
10/12/04	21-357	Labeling Request: Proving Annotated Labeling for NDA-21-357 in PDF and Word Format.
10/28/04	21-357/ 21-358	Labeling Request: Proving remaining labeling (vial, carton) for NDA-21-357 and all labeling for 21-358 in PDF and Word Format.
11/10/04	21-357/ 21-358	From FDA: Labeling Questions to Sponsor and FDA's Proposed Labeling.
11/12/04	21-357/ 21-358	Response to FDA Facsimile date Nov 10, 2004: Response to 3 comments and proposed labeling text.
11/18/04	21-357/ 21-358	From FDA: Proposed Labeling, Including acceptance of changes and additional comments/edits to Labeling
11/18/04	21-357/ 21-358	From FDA: Phase 4 Commitments for Efficacy and Safety Study and Pharmacokinetic Study in Pediatric Patients with suspected or known CNS disease.

Product: MultiHance® (gadobenate dimeglumine injection)
NDA # 21-357/21-358 and 21-522/21-523

NDA Correspondence Log

<u>Date</u>	<u>NDA No.</u>	<u>Description</u>
11/22/04	21-357/ 21-358	From FDA: Pharm/Tox Labeling for Pregnancy Category and Change of Wording of Phase 4 commitments (from Treatment to evaluation of CNS disease in pediatric patients).
11/22/04	21-357/ 21-358	Acceptance of proposed changes for Pregnancy C Labeling and also the Phase 4 commitment wording.
11/23/04	21-357/ 21-358	From FDA: Approval Letter for IV Use in MRI of the CNS in adults to visualize lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine and associated tissues