

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: FRESENIUS	§	MDL NO. 1:13-MD-2428-DPW
GRANUFLO/NATURALLYTE	§	
DIALYSATE	§	
PRODUCTS LIABILITY LITIGATION	§	
_____	§	
	§	
<i>THIS DOCUMENT RELATES TO ALL</i>	§	
<i>CASES</i>	§	
_____	§	

CASE MANAGEMENT ORDER NO. 6
(Regarding Plaintiff Fact Sheets and Defendant Fact Sheets)

I. PLAINTIFF FACT SHEET

1. Service of Plaintiff Fact Sheets and HIPAA Authorizations:

a. As set forth in Case Management Order (“CMO”) No. 2, each Plaintiff in an action pending and served before the Court in MDL No. 2428 shall serve a completed Plaintiff Fact Sheet (“PFS”), the form of which has been agreed to by the parties and approved by the Court and is attached hereto as Exhibit “A.”

b. Along with the PFS, each Plaintiff shall provide a *HIPAA Authorization* in the form attached at Exhibit “B.” Plaintiffs may choose whether to provide one *HIPAA Authorization* that allows Defendants to fill in the information for each of Plaintiffs’ Health Care Providers, or to provide a *HIPAA Authorization* for every Health Care Provider identified in the PFS. If a review of Plaintiff’s medical records reveals additional Health Care Providers from whom Defendants wish to seek medical records, Plaintiff shall provide additional *HIPAA Authorizations* for those providers within ten (10) days of a request from Defendants.

2. **Deadlines for Service of the Fact Sheets:**

a. **Fresenius Clinic Cases-** In any case currently pending in this MDL where the injury/death is alleged to have been the result of treatment at a Fresenius Medical Care North America (“FMCNA”) dialysis clinic and counsel for Plaintiff did not obtain the patient’s clinic medical chart prior to the filing of the complaint, the deadlines for the exchange of PFS and the Defendants Fact Sheet (“DFS”) is set forth in CMO No. 3. The deadlines for the exchange of Plaintiff and Defendants Fact Sheets in all other currently pending cases involving an FMCNA dialysis clinic are set forth at paragraphs 4(b) and 4(c) of CMO No. 2.

b. **Non-Fresenius Clinic Cases-** The deadline for the exchange of the PFS and DFS for cases currently pending in this MDL where the injury or death is alleged to have been the result of treatment at a non-FMCNA dialysis clinic as set forth in CMO No. 2, paragraphs 4 (b) and (c) are hereby extended thirty (30) days such that the PFS shall be served no later than December 27, 2013 and the DFS shall be served no later than February 25, 2014.

c. **Newly Filed or Transferred Cases-** The deadlines for the exchange of the PFS and DFS in cases that are newly filed or transferred into this MDL after the date of the entry of this Order are set forth in paragraph 4(d) of CMO No. 2, except that in newly filed or transferred cases where the injury/death is alleged to have been the result of treatment at an FMCNA clinic and counsel for Plaintiff did not request the patient’s clinic medical chart prior to the filing of the Complaint, the deadlines for the exchange of the PFS and DFS may be extended pursuant to Paragraph 9 of CMO No. 3.

3. **Method of Service of PFS and Related Documents:**

a. **E-mail and Mail Service-** Service of the PFS and service of any documents required under CMO No. 3 shall be by mail and E-mail at:

Darrell Tucker
Bradley ArantBoult Cummings, LLP
One Federal Place
1819 Fifth Avenue North
Birmingham, AL 35203-2119

GranuFloPlaintiffCaseInformation@babco.com

b. Service of the complete PFS as set forth in paragraph 1(d) above shall be deemed good and sufficient service for all U.S. based Fresenius Defendants.

4. If a Plaintiff does not submit a PFS within the time specified in this Order, or submits a PFS that contains a material deficiency,¹ Defendants may take the following steps:

a. **Overdue PFS:** In cases where the Plaintiff does not submit a PFS within the time specified in this Order, Defendants may send a *Notice of Overdue Fact Sheet* to that Plaintiff's counsel of record within fifteen (15) days after the date the PFS was due. Said *Notice of Overdue Fact Sheet* shall permit an additional thirty (30) days to serve a completed PFS. In the event a Plaintiff does not provide the completed PFS by the expiration of the additional thirty (30) day period, Defendants may, after conducting the prerequisite meet and confer, move for relief under Fed. R. Civ. P. 37(b)(2).

b. **Materially Deficient PFS:** In cases where the Plaintiff submits a materially deficient PFS within the time specified in this Order, Defendants may send a *Notice of Materially Deficient Fact Sheet* to that Plaintiff's counsel of record within thirty (30) days after the date the PFS was due, provided however that if the number of PFS's received within five business days is 200 or more, the deadline for sending the *Notice of Materially Deficient Fact*

¹ As used herein, a materially deficient PFS or DFS means a deficiency that prejudices the opposing party through a failure to provide necessary information, thereby impeding that parties' access to material and relevant evidence.

Sheet shall be extended to sixty (60) days. Said *Notice of Materially Deficient Fact Sheet* shall permit an additional thirty (30) days to cure the material deficiency in the PFS. In the event a Plaintiff does not cure the deficiency by the expiration of the additional thirty (30) day period, Defendants may, after conducting the prerequisite meet and confer, move for relief under Fed. R. Civ. P. 37(b)(2). Plaintiff shall have fourteen (14) days to file an opposition, if any.

c. Defendants shall send a copy of all *Notices of Overdue or Materially Deficient Fact Sheets* and copies of any and all motions to dismiss under this paragraph to Plaintiffs' Liaison Counsel by E-mail at GranufloPFSDeficiency@Kreindler.com.

5. The admissibility of information in the PFS shall be governed by the Federal Rules and no objections are waived by virtue of any PFS response.

6. All information contained in the PFS is confidential and protected under the Protective Order (CMO No. 5).

II. DEFENDANT FACT SHEET

7. Defendants Fresenius USA, Inc., Fresenius Medical Care Holdings, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc. (collectively "Fresenius North America") shall serve a completed Defendant Fact Sheet ("DFS"), as set forth in CMO No. 2 and CMO No. 3, the form of which has been agreed to by the parties and approved by the Court and which is attached hereto as Exhibit "C."

8. The deadlines outlined in paragraph 1(c) above govern the timing for service of the DFS.

9. The completed DFS shall be served in an electronic form on the attorney identified on page one of the PFS. The method of service shall be by E-mail and regular mail. Additionally, a Notice of Service of the DFS shall be served by E-mail upon the attorney


identified on page one of the PFS and also on the Plaintiffs Liaison Counsel at GranufloDFS@kreindler.com.

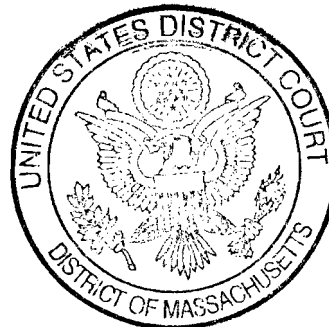
10. If Defendants do not submit a DFS within the time specified in this Order, as set forth in paragraph 1(b) above, or submit a DFS that contains a material deficiency counsel for Plaintiff may send a *Notice of Overdue or Materially Deficient Fact Sheet* to counsel for Fresenius North America as set forth in paragraph 1(c) above, within thirty (30) days after the date that the DFS was due. Said *Notice of Overdue or Materially Deficient Fact Sheet* shall permit Fresenius North America additional thirty (30) days to cure the overdue or materially deficient DFS. In the event Fresenius North America fails to provide the completed DFS or cure the material deficiency by the expiration of the thirty (30) day period, Plaintiff's counsel shall consult with MDL Lead/Liaison Counsel, who may move for appropriate relief from the Court as set forth in paragraph 12 of CMO No. 2. Fresenius North America shall have fourteen (14) days to file an opposition, if any. Plaintiffs shall send a copy of all *Notices of Overdue or Materially Deficient Fact Sheets* to Plaintiffs' Liaison Counsel (at the E-mail address set forth in paragraph 2(c) above).

11. The admissibility of information in the DFS shall be governed by the Federal Rules and no objections are waived by virtue of any DFS response.

12. All information contained in the DFS is confidential and protected under the Protective Order (CMO No. 5).

IT IS SO ORDERED.


DOUGLAS P. WOODLOCK,
UNITED STATES DISTRICT JUDGE



**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE: FRESINIUS
GRANUFLO/NATURALYTE DIALYSATE
PRODUCTS LIABILITY LITIGATION**

MDL NO. 1:13-MD-2428-DPW

PLAINTIFF FACT SHEET

In completing this Plaintiff Fact Sheet, you must provide information that is true and correct to the best of your knowledge. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. You must also supplement your responses in the event that you later learn or receive additional information that is responsive to any of the information requests below. In the event the Plaintiff Fact Sheet does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary. Please identify any documents that you are producing as responsive to a question or request by bates-stamp identifiers.

If you are completing this Plaintiff Fact Sheet in a representative capacity, please respond to the questions on behalf of the person you are representing whom you allege was exposed to, or treated with, GranuFlo and/or NaturaLyte. Whether you are completing this fact sheet for yourself or for someone else, please assume that "you" or "Plaintiff" means the person who was exposed to, or treated with, GranuFlo and/or NaturaLyte.

This Fact Sheet shall be completed in accordance with Case Management Orders 2 and 3. The information provided is confidential and subject to the protective order.

[Note: In an effort to be forthcoming and to provide non-privileged information, the information provided in this fact sheet is, by necessity, not based solely upon the knowledge of the plaintiff and includes non-privileged information assembled and collected by the parties' attorneys which may not be known to the executing party.]

I. CASE INFORMATION

Caption: _____ Date Filed: _____

Docket No. (Including Court): _____

Plaintiff's Attorney and Contact Information, Including Telephone Number:

CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Name, Title and Contact Information of Each Person Providing Responses to this Fact Sheet:

II. PLAINTIFF'S INFORMATION

Full Name of Plaintiff: _____

Last Address: _____

Date of Birth: _____

Plaintiff's FMS Medical Record Number, also known as the Patient Identification Number:

If no FMS Medical Record Number, please provide the following information:

a. Plaintiff's Medicare Identification Number: _____

b. The last four digits of Plaintiff's Social Security Number: _____

Please provide the following information:

1. Date of Death/Injury: _____

2. Location of Death/Injury (Clinic, Home, Hospital, including name of clinic or hospital, if applicable, and complete address) _____

3. Cause of Death/Injury asserted by Plaintiff as of the date of this Fact Sheet:

Non-Cardiac Event or Condition

Cardiac Event or Condition

Acute Coronary Syndrome

Arrhythmia

Bradycardia Arrhythmia

CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- Cardiomegaly
- Cardiomyopathy
- Congestive Heart Failure
- Coronary Artery Disease
- Coronary Occlusion
- Coronary Thrombosis
- Myocardial Infarction
- Sudden Cardiac Arrest
- Cardiopulmonary Arrest
- Tachycardia Arrhythmia
- Atrial Fibrillation
- Ventricular Fibrillation
- Other (please specify)
- Unknown

Do not know

4. Was Autopsy Performed? _____ If So, Date _____

ATTACH DEATH CERTIFICATE AND AUTOPSY REPORT, IF APPLICABLE.

5. Please provide a list of all treating physicians or healthcare providers who provided medical care to Plaintiff within the twelve (12) months preceding the injury/death, including but not limited to all primary care physicians, cardiologists, nephrologists, and hospitals.

a. Provider Name: _____

Provider Address: _____

Type of Provider: _____

b. Provider Name: _____

Provider Address: _____

Type of Provider: _____

- c. Provider Name: _____
Provider Address: _____
Type of Provider: _____

ATTACH ADDITIONAL SHEETS AS NECESSARY

III. REPRESENTATIVE/DEMOGRAPHIC INFORMATION

1. Name of Representative: _____
2. Relationship to Plaintiff (if applicable): _____
3. Address: _____
4. Appointed Position (if applicable): _____
5. Court of Appointment: _____
6. Date of Appointment: _____

IV. DIALYSIS HISTORY

1. List all dialysis clinics and/or dialysis facilities, including hospital-operated acute and chronic dialysis units, and including home hemodialysis, where the Plaintiff received dialysis treatments.
- a. Dialysis Clinic Name: _____
Clinic Address: _____
- b. Dialysis Clinic Name: _____
Clinic Address: _____
- c. Dialysis Clinic Name: _____
Clinic Address: _____

ATTACH ADDITIONAL SHEETS AS NECESSARY

CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

2. Please provide the date of Plaintiff's last dialysis treatment prior to or at the time of death/injury: _____

a. Please provide the name and address of the dialysis provider: _____

PLEASE PROVIDE ALL NON-PRIVILEGED, RELEVANT MEDICAL RECORDS, INCLUDING BUT NOT LIMITED TO DIALYSIS TREATMENT RECORDS, IN YOUR POSSESSION, CUSTODY OR CONTROL THAT HAVE NOT ALREADY BEEN PRODUCED PURSUANT TO CASE MANAGEMENT ORDER NO. 3

CERTIFICATION

I declare that all of the information provided in this Plaintiff Fact Sheet is true and correct to the best of my knowledge and that I have supplied all requested documents to the extent that such documents are in my possession, custody and control (including the custody and control of my lawyers).

Signature

Print Name

Date

AUTHORIZATIONS

Provide ONE (1) SIGNED ORIGINAL copy of each of the records authorization forms attached as Ex. B to CMO No. 6. These authorization forms will authorize the records vendor selected by the parties to obtain those records from the providers identified within this Plaintiff Fact Sheet.

Date: _____

Signature of Plaintiff's Counsel

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

Patient Name:	Date of Birth:	Social Security Number:
Patient Address:		

I, or my authorized representative, request that health information regarding my care and treatment be released as set forth on this form.

In accordance with the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. 164.508, I understand that:

1. This authorization may include disclosure of information relating to alcohol and drug abuse, mental health treatment, except psychotherapy notes, and confidential HIV related information, only if I place my initials on the appropriate line in Item 11(a). In the event the health information described below include any of these types of information, and I initial the line on the box in Item 11(a), I specifically authorize release of such information to the person(s) indicated in Item 10.
2. If I am authorizing the release of HIV-related, alcohol or drug treatment, or mental health treatment information, the recipient is prohibited from redisclosing such information without my authorization unless permitted to do so under federal or state law. I understand that I have a right to request a list of people who may receive or use my HIV-related information without authorization.
3. I have the right to revoke this authorization at any time by writing to the health care provider listed below. I understand that I may revoke this authorization except to the extent that action has already been taken based on this authorization.
4. I understand that signing this authorization is voluntary. My treatment, payment, enrollment in a health plan, or eligibility for benefits will not be conditioned upon my authorization of this disclosure. Any photostatic copy of this document shall have the same authority as the original, and may be substituted in its place.
5. Information disclosed under this authorization might be redisclosed by the recipient, and this redisclosure may no longer be protected by federal or state law, except as noted in Item 2.
6. This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).
7. This authorization shall be valid through December 31, 2016 or the conclusion of my case, whichever occurs first; unless it is revoked as provided in Item 3, and shall remain in full force and effect until such expiration, and further authorizes the Provider to release to the Recipient any additional records created or obtained by the Provider after the date hereof. The records requester has agreed to pay reasonable charges made by the Provider to supply copies of such records.
8. This authorization specifically does NOT authorize the release of original documents and materials, including tissue slides, tissue blocks and tissue samples.

9. Name and address of health provider or entity to release this information:	
10. Name and address of entity(ies) to whom this information will be mailed or sent:	Name and address of entity as designee to whom this information will be mailed or sent:

HIPPA AUTHORIZATION FOR THE RELEASE OF HEALTHCARE RECORDS

11(a). Specific information to be released: <input checked="" type="checkbox"/> Medical Records and patient data (See CMO - ___ in MDL No. 2428) <input checked="" type="checkbox"/> Entire Medical Record, including, but not limited to, patient histories, office notes (except psychotherapy notes, biopsy/pathology specimens and/or materials, and autopsy materials), diagnoses, analyses, progress reports, laboratory reports, test results, x-rays, radiology reports, radiology films or scans (in any form), referrals, consults, billing records, correspondence, prescription records, autopsy reports, pathology reports, death certificates, consents for treatment, insurance records, and records sent to you by other health care providers. <input type="checkbox"/> Other: _____ Include: (Indicate by Initialing) _____ Alcohol/Drug Treatment _____ Mental Health Information _____ HIV-Related Information	
Authorization to Discuss Health Information 11(b) <input type="checkbox"/> By Initialing here _____ I authorize _____ Name of individual health care provider to discuss my health information with my attorney, or a governmental agency listed here: _____ (Attorney/Firm Name or Governmental Agency Name)	
<p>***This authorization does not authorize you to discuss my health information or medical care with anyone other than the attorney or governmental agency specified in Item 11(b).</p>	
12. Reason for release of information: <input type="checkbox"/> At request of individual <input checked="" type="checkbox"/> Other: Litigation	13. Date or event on which this authorization will expire: December 31, 2016 or at the conclusion of the case, whichever occurs first.
14. If not the patient, name of person signing form:	15. Authority to sign on behalf of patient:

All items on this form have been completed and my questions about this form have been answered. In addition, I have been provided a copy of the form.

 Signature of patient or authorized representative

Date: _____

ACKNOWLEDGMENT

The undersigned, as the record requester named in the above medical authorization, hereby declares under penalty of perjury, pursuant to 28 U.S.C. Section 1746, that the attorney to the patient named in the foregoing medical authorization has been given notice that the authorization will be used to request records from the person or entity to whom it is addressed, and the attorney has been given five (5) days advance notice and has been afforded an opportunity to object to the request and any objections have been resolved. The attorney for the patient named in the foregoing medical authorization has also been afforded an opportunity to order copies of the records from the undersigned requestor at a reasonable cost.

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: FRESENIUS	:	
GRANUFLO/NATURALYTE DIALYSATE	:	MDL NO. 1:13-MD-2428-DPW
PRODUCTS LIABILITY LITIGATION	:	
	:	
	:	
	:	

DEFENDANT FACT SHEET

For each case, Fresenius USA, Inc., Fresenius Medical Care Holdings, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc. (collectively "Defendant") must complete this Defendant Fact Sheet ("DFS"). In completing this DFS, you must provide information that is true and correct to the best of your knowledge. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. In the event the DFS does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary. Please identify any documents that you are producing as responsive to a question or request by bates-stamp identifiers.

This DFS must be completed and served on all counsel identified as representing the plaintiff in Section I of the Plaintiff's Fact Sheet.

The terms "you," "your" or "yours" means the responding defendant.

The term "Plaintiff" refers to the injured party.

The phrase "Health Care Provider" means each of the Plaintiff's physicians or medical providers, including dialysis facilities and nephrologists.

This Fact Sheet shall be completed in accordance with Case Management Orders 2 and 3. The information provided is confidential and subject to the protective order.

[Note: In an effort to be forthcoming and to provide non-privileged information, the information provided in this fact sheet is, by necessity, not based solely upon the knowledge of the defendant and includes non-privileged information assembled and collected by the parties' attorneys which may not be known to the executing party.]

L. CASE INFORMATION

Caption: _____ **Date Filed:** _____

Docket No.: _____

Plaintiff: _____

Name, Title and Contact Information of Each Person Providing Responses to this Fact Sheet: _____

II. PRODUCT IDENTIFICATION

1. Did you distribute GranuFlo acid concentrate to the clinic, facility, or hospital where Plaintiff received the last dialysis treatment prior to injury/death as identified in Section IV of the Plaintiff's Fact Sheet (the "Named Facility") during the twelve (12) month period of time preceding the date of injury/death?

Yes No Don't Know

2. If your answer is "yes" to Question 1 above, please provide a list of all shipments of GranuFlo acid concentrate to the Named Facility for the period of twelve (12) months prior to the alleged injury/death to Plaintiff through the date of injury or death and include the dates of shipment or distribution.

3. If your answer is "don't know" to Question 1 above and you have reason to believe that GranuFlo acid concentrate may have been shipped to the Named Facility by a distributor (i.e., contractors, subcontractors and agents) and records pertaining to that shipment reside with the distributor, please identify the distributor.

4. Please provide a complete set of product labels used for GranuFlo acid concentrate from January 2003 through October 2013 and associate each label with the code numbers to which they are applicable.

5. Does data uploaded from the Fresenius Medical Service clinic medical chart and compiled in the Data Warehouse indicate that GranuFlo acid concentrate with a composition of 8 meq/L of acetate was prescribed for this patient in the twelve (12) month period preceding the injury/death:

6. Please indicate below the model of the Fresenius dialysis machine in use by the Plaintiff's at the time of the Plaintiff's alleged injury or death at the facility identified in Section IV.2 of the Plaintiff's Fact Sheet (the "Named Facility"):

Model 2008K:

Model 2008H:

Model 2008K2:

Model 2008T:

Other: _____

Unknown:

III. PLAINTIFF'S HEALTHCARE PROVIDERS

1. Dear Doctor/Dear Healthcare Provider Letters

A. Please provide a full set of "Dear Doctor" or "Dear Healthcare Provider" letters or memoranda issued by the FMS Chief Medical Office related to acid concentrate products for the years 2000 through 2012, together with a compilation of the physicians to whom the letters or memoranda were made available either through direct transmission or through access to the FMS Doctor's Corner website, and the date on which such access was given to each physician, if any.

B. For each "Dear Doctor" or "Dear Healthcare Provider" that was sent to Plaintiff's dialysis clinic(s), please identify any and all lists or databases that demonstrate that these letters were sent to our clients' treating physicians, and provide documentation that identifies that the letter was sent, if any.

C. Please provide copies of any "Reply Forms" returned in response to the "Dear Doctor" or "Dear Healthcare Provider" letters, if any.

2. Identity of Plaintiff's Dialysis Facility Director, Patient Care Technician(s) and Other Providers

For cases involving a Fresenius dialysis facility, please identify the Medical Director at the Named Facility at the time of Plaintiff's injury or death. To the extent not legible in Plaintiff's medical records produced in accordance with CMO 3, please identify to the extent possible the persons whose names are entered but not legible on the day of Plaintiff's last dialysis treatment

prior to injury/death.

IV. PLAINTIFF INFORMATION

1. Do you have in your possession any Medwatch FDA Forms 3500A filed with the FDA related to Plaintiff?

Yes

No

2. Do you have in your possession any internal product complaints recorded by the Renal Therapies Group's pharmacovigilance department related to Plaintiff?

Yes

No

3. Do you have in your possession any Fresenius "Reports of Clinical Variance" related to Plaintiff?

Yes

No

If your answer to any of the above three questions is "yes," please either provide a copy of the document(s) described above or state that a privilege is being asserted with respect to such document(s).

4. Was Plaintiff one of the 941 hemodialysis patients who were the subjects of the Fresenius study described in the internal company memo dated November 4, 2011?

Yes

No

If your answer to the above question is "yes," please provide any documents pertaining to the Plaintiff and his/her relationship to the above-referenced study.

5. Did you or any consultant perform an analysis, adjudication, or review of medical or scientific information concerning the Plaintiff, his or her use of Granuflo, and the potential for Granuflo to cause injury and or death to the Plaintiff?

Yes

No

Unknown

If your answer to the above question is "yes," please identify the person(s) performing the analysis or review, their current address, and produce all documents relating to the analyses performed concerning the Plaintiff. (Note: This request does not require Defendant to reveal or

produce information or documents protected by privilege, including, but not limited to, work product of attorneys or retained consulting experts.)

CERTIFICATION

I declare that all of the information provided in this Defendant Fact Sheet is true and correct to the best of my knowledge and that I have supplied all requested documents to the extent that such documents are in my possession, custody and control (including the custody and control of my lawyers).

Signature

Print Name

Date