

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	OSTROW; Gregory I. et al.	Group Art Unit:	Not yet assigned
Serial Number:	16/805,612	Examiner:	Not yet assigned
Filing or 371 (c) Date:	2020-02-28	<b>CONFIRMATION NO:</b>	<b>8996</b>
Title:	D2O STABILIZED PHARMACEUTICAL FORMULATIONS		

FILED ELECTRONICALLY ON: March 2, 2020

Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR § 1.97**

Commissioner for Patents:

An Information Disclosure Statement along with attached PTO/SB/08 is hereby submitted. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

The Examiner is requested to review the information provided and to make the information of record in the above-identified application. The Examiner is further requested to initial and return the attached PTO/SB/08 in accordance with MPEP § 609.

The right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered, is hereby reserved.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in § 1.56.

- A. ☒ *37 CFR § 1.97 (b)*. This Information Disclosure Statement should be considered by the Office because:
- ☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under § 1.53 (d);  
-- OR --
  - ☐ (2) It is being filed within 3 months of entry of the national stage as set forth in § 1.491 in an international application;  
-- OR --
  - ☒ (3) It is being filed before the mailing of a first Office action on the merits;  
-- OR --
  - ☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- B. ☐ *37 CFR § 1.97(c)*. Although this Information Disclosure Statement is being filed after the period specified in *37 CFR § 1.97(b)*, above, it is filed before the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, this Information Disclosure Statement should be considered because it is accompanied by one of:
- ☐ a statement as specified in §1.97 (e) provided concurrently herewith;  
-- OR --
  - ☐ a fee of \$240.00 as set forth in § 1.17 (p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C. ☐ *37 CFR § 1.97 (d)*. Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under § 1.113, (2) a notice of allowance under § 1.311, or (3) an action that otherwise closes prosecution in the application, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in § 1.97 (e);  
-- AND --
  - ii. a fee of \$240.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D. ☐ *37 CFR §1.97 (e)*. Statement.
- ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (c);  
-- AND/OR --
  - ☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§ 1.97 (d);  
-- AND/OR --
  - ☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e) (1) as provided for under MPEP 609.04(b) V.

- E. ☐ *Statement Under 37 C.F.R. §1.704(d).* Each item of information contained in the information disclosure statement was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office or is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.
- F. ☒ *37 CFR §1.98 (a) (2).* The content of the Information Disclosure Statement is as follows:
- ☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- OR --
- ☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are not enclosed.
- AND/OR --
- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).
- AND/OR --
- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98 (a) (2) (iii).
- G. ☒ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.
- ☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.
- OR --
- ☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: \_\_\_\_\_
- ☒ Pursuant to 37 CFR §1.98(a) (3) (ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.
- H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:
- ☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement, or cited by examiner for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.
- Application in which the information was submitted: \_\_\_\_\_
- Information Disclosure Statement(s) filed on: \_\_\_\_\_
- AND
- ☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

- I. ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.46682-702.301).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: March 2, 2020

By: /Stephanie Dusaban Gonzales/  
Stephanie Dusaban Gonzales, Reg. No. 75016

650 Page Mill Road  
Palo Alto, CA 94304-1050  
(650) 493-9300  
Customer No. 21971

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	16805612
Filing Date	02-28-2020
First Named Inventor	OSTROW; Gregory I.
Art Unit	
Examiner Name	Not yet assigned
Attorney Docket Number	46682-702.301

Sheet 1 of 11

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	001	US-3863633	02-04-1975	RYDE; Emma Marta. et al.	
	002	US-4014335	03-29-1977	ARNOLD; Randall K.	
	003	US-4474751	10-02-1984	HASLAM; John L. et al.	
	004	US-4938763	07-03-1990	DUNN; Richard L. et al.	
	005	US-5033252	07-23-1991	CARTER; Douglas V.	
	006	US-5052558	10-01-1991	CARTER; Douglas V.	
	007	US-5147647	09-15-1992	DAROUGAR; Sohrab.	
	008	US-5259998	11-09-1993	REICH; Cary. et al.	
	009	US-5260000	11-09-1993	NANDU; Mahendra P. et al.	
	010	US-5323907	06-28-1994	KALVELAGE; John D.	
	011	US-5324519	06-28-1994	DUNN; Richard L. et al.	
	012	US-5702716	12-30-1997	DUNN; Richard L. et al.	
	013	US-5716952	02-10-1998	WOLDEMUSSIE; Elizabeth et al.	
	014	US-5744153	04-28-1998	YEWEE; Gerald L. et al.	
	015	US-5858375	01-12-1999	FURMINGER; Ian George Stephen. et al.	
	016	US-5900360	05-04-1999	WELCH; William J. et al.	
	017	US-5990194	11-23-1999	DUNN; Richard L. et al.	
	018	US-6139870	10-31-2000	VERRECCHIA; Thierry.	
	019	US-6218428	04-17-2001	CHYNN; Emil et al.	
	020	US-6270954	08-07-2001	WELCH; William J. et al.	
	021	US-6410048	06-25-2002	FOTINOS; Spiros.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional).<sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.<sup>5</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	16805612
Filing Date	02-28-2020
First Named Inventor	OSTROW; Gregory I.
Art Unit	
Examiner Name	Not yet assigned
Attorney Docket Number	46682-702.301

Sheet 2 of 11

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	022	US-6503497	01-07-2003	CHOWHAN; Masood. et al.	
	023	US-6720001	04-13-2004	CHEN; Feng-Jing et al.	
	024	US-7691099	04-06-2010	BERRY; Michael J.	
	025	US-7858582	12-28-2010	JIN; Lei. et al.	
	026	US-8333985	12-18-2012	KNAACK; David. et al.	
	027	US-8980839	03-17-2015	MITRA; Ashim K. et al.	
	028	US-9421199	08-23-2016	OSTROW; Gregory I. et al.	
	029	US-9770447	09-26-2017	OSTROW; Gregory I. et al.	
	030	US-10076515	09-18-2018	OSTROW; Gregory I. et al.	
	031	US-10201534	02-12-2019	OSTROW; Gregory I. et al.	
	032	US-10251875	04-09-2019	PURI; Navneet. et al.	
	033	US-2018147214	05-31-2018	OSTROW; Gregory I. et al.	
	034	US-20030157187	08-21-2003	HUNTER; William L.	
	035	US-20050249770	11-10-2005	HUNTER; William L.	
	036	US-20060159771	07-20-2006	KADRMAS; Eddie F. et al.	
	037	US-20070207192	09-06-2007	HOLL; Richard. et al.	
	038	US-20070280992	12-06-2007	MARGARON; Philippe M.C. et al.	
	039	US-20080113035	05-15-2008	HUNTER; William L.	
	040	US-20080153900	06-26-2008	HUNTER; William L.	
	041	US-20100022495	01-28-2010	HOTAMISLIGIL; Gokhan S. et al.	
	042	US-20100196285	08-05-2010	BAYERL; Thomas.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional).<sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	16805612
Filing Date	02-28-2020
First Named Inventor	OSTROW; Gregory I.
Art Unit	
Examiner Name	Not yet assigned
Attorney Docket Number	46682-702.301

Sheet 3 of 11

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	043	US-20100256557	10-07-2010	LUST; Victor. et al.	
	044	US-20120001503	01-05-2012	OWNG; Rong-Jong. et al.	
	045	US-20120015035	01-19-2012	WILDSOET; Christine F. [Us] et al.	
	046	US-20120028910	02-02-2012	COMBAL; Jean-Philippe. et al.	
	047	US-20120135084	05-31-2012	BAYERL; Thomas.	
	048	US-20120203161	08-09-2012	HEREKAR; Satish V.	
	049	US-20120277694	11-01-2012	ODRICH; Steven A. et al.	
	050	US-20130302855	11-14-2013	SELBER; Klaus. et al.	
	051	US-20140011761	01-09-2014	HOTAMISLIGIL; Gokhan S. et al.	
	052	US-20140088199	03-27-2014	SHARMA; Anant.	
	053	US-20140343030	11-20-2014	LI; Yun-Long. et al.	
	054	US-20140350049	11-27-2014	HOVNANIAN; Alain. et al.	
	055	US-20150290125	10-15-2015	HORN; Gerald. et al.	
	056	US-20160009705	01-14-2016	OSTROW; Gregory I. et al.	
	057	US-20190091213	04-12-2019	OSTROW; Gregory I. et al.	
	058	US-20190298707	10-03-2019	OSTROW; Gregory I. et al.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	16805612
				Filing Date	02-28-2020
				First Named Inventor	OSTROW; Gregory I.
				Art Unit	
				Examiner Name	Not yet assigned
Sheet	4	of	11	Attorney Docket Number	46682-702.301

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	001	CN-101327216-A	12-24-2008	ZHENGLIAN XIAO [CN]	Abstract:	<input checked="" type="checkbox"/>
	002	CN-101468214-A	07-01-2009	SHANGHAI HUAJIE EYE MEDICAL EQ [CN]	Machine Translation:	<input checked="" type="checkbox"/>
	003	CN-1456161-A	11-19-2003	LIU JIDONG [CN]	Abstract:	<input checked="" type="checkbox"/>
	004	DE-1182388-B	11-26-1964	BAYER AG.	English counterpart:GB9416 94	<input checked="" type="checkbox"/>
	005	DE-1518819-B1	12-04-1969	BASF AG.	Abstract:	<input checked="" type="checkbox"/>
	006	EP-0332826-A1	09-20-1989	TEVA PHARMA [IL]		<input type="checkbox"/>
	007	WO-0049990-A2	08-31-2000	KHAMAR BAKULESH MAFATLAL [IN]		<input type="checkbox"/>
	008	WO-02096418-A1	12-05-2002	VALLEY FORGE PHARMACEUTICA LS [US], et al.		<input type="checkbox"/>
	009	WO-2008005053-A1	01-10-2008	CYDEX INC [US], et al.		<input type="checkbox"/>
	010	WO-2008008330-A2	01-17-2008	NTK ENTPR INC [US], et al.		<input type="checkbox"/>

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(Use as many sheets as necessary)</p>				<b>Complete if Known</b>	
				Application Number	16805612
				Filing Date	02-28-2020
				First Named Inventor	OSTROW; Gregory I.
				Art Unit	
				Examiner Name	Not yet assigned
				Attorney Docket Number	46682-702.301
Sheet	5	of	11		

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	011	WO-2010083129-A2	07-22-2010	UNIV CALIFORNIA [US], et al.		<input type="checkbox"/>
	012	WO-2011019940-A2	02-17-2011	SEROS MEDICAL LLC [US], et al.		<input type="checkbox"/>
	013	WO-2011098578-A2	08-18-2011	BIONEER AS [DK], et al.		<input type="checkbox"/>
	014	WO-2011137449-A2	11-03-2011	SEROS MEDICAL LLC [US], et al.		<input type="checkbox"/>
	015	WO-2012111029-A2	08-23-2012	M S APPASAMY ASSOCIATES [IN], et al.		<input type="checkbox"/>
	016	WO-2012161655-A1	11-29-2012	SINGAPORE HEALTH SERV PTE LTD [SG], et al.		<input type="checkbox"/>
	017	WO-2013166385-A1	11-07-2013	KALA PHARMACEUTICA LS INC [US], et al.		<input type="checkbox"/>
	018	WO-2014140105-A1	09-18-2014	D2 BIOSCIENCE GROUP LTD., et al.		<input type="checkbox"/>
	019	WO-2015200361-A1	12-30-2015	SYDNEXIS INC [US]		<input type="checkbox"/>
	020	WO-2016172712-A2	10-27-2016	SYDNEXIS INC [US]		<input type="checkbox"/>

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	16805612
				Filing Date	02-28-2020
				First Named Inventor	OSTROW; Gregory I.
				Art Unit	
				Examiner Name	Not yet assigned
Sheet	6	of	11	Attorney Docket Number	46682-702.301

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	021	WO-2016196367-A1	12-08-2016	SYDNEXIS INC [US]		<input type="checkbox"/>
	022	WO-2018154440-A1	08-30-2018	SINGAPORE HEALTH SERV PTE LTD [SG]		<input type="checkbox"/>
	023	WO-9421298-A1	09-29-1994	PASTEUR INSTITUT [FR], et al.	Abstract:	<input checked="" type="checkbox"/>
	024	WO-9624331-A1	08-15-1996	USTAV MAKROMOLEKUL ARNI CHEMIE [CZ], et al.		<input type="checkbox"/>
	025	WO-9716192-A1	05-09-1997	MERCK & CO INC [US], et al.		<input type="checkbox"/>

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	16805612
				Filing Date	02-28-2020
				First Named Inventor	OSTROW; Gregory I.
				Art Unit	
				Examiner Name	Not yet assigned
				Attorney Docket Number	46682-702.301
Sheet	7	of	11		

### NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T <sup>2</sup>
	001	ABRAHAM et al. Draize rabbit eye test compatibility with eye irritation thresholds in humans: a quantitative structure-activity relationship analysis. Toxicol Sci 76:384-391 (2003).	<input type="checkbox"/>
	002	BADARO et al. Retinal biocompatibility of brilliant Blue G with deuterated water for chromovitrectomy. J. Ophthalmic and Vision Research 9(2): 204-209 (2014).	<input type="checkbox"/>
	003	CHASIN et al. Polyanhydrides for Controlled Drug Delivery. Biopharm pgs. 33-46 (1988).	<input type="checkbox"/>
	004	CHENG et al. Water movement in the rabbit eye. Exp. Eye Res. 52:337-339 (1991).	<input type="checkbox"/>
	005	CHENG. Fate of water in the soft contact lens immediately after lens placement onto the cornea. Optometry and Vision Science 68(6):414-417 (1991).	<input type="checkbox"/>
	006	CHIRIERI et al. Investigations concerning the changes induced by deuterium for hydrogen substitution in bioelectric activity of the frog retina. Physiologie 14(2):119-123 (1977).	<input type="checkbox"/>
	007	CRIADO et al. Scavenging of photogenerated oxidative species by antimuscarinic drugs: atropine and derivatives. Redoc Rep 7(6):385-394 (2002).	<input type="checkbox"/>
	008	DOUGLAS et al. Nanoparticles in Drug Delivery. CRC Crit. Rev. Therap. Drug Carr Syst 3:233-261 (1987).	<input type="checkbox"/>
	009	FANG et al. Prevention of Myopia Onset with 0.025% Atropine in Premyopic Children. Journal of Ocular Pharmacology and Therapeutics 26(4):341-345 (2010).	<input type="checkbox"/>
	010	GANEVA. Heavy water effect on certain energetic processes in retina. Physiologie 6(1):59-62 (1979).	<input type="checkbox"/>

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**  
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Substitute for form 1449/PTO  <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(Use as many sheets as necessary)</p>				<b>Complete if Known</b>	
				Application Number	16805612
				Filing Date	02-28-2020
				First Named Inventor	OSTROW; Gregory I.
				Art Unit	
				Examiner Name	Not yet assigned
				Attorney Docket Number	46682-702.301
Sheet	8	of	11		

### NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author(in CAPITAL LETTERS), title of the article(when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	011	GARCIA-VALLDECABRES et al. pH Stability of ophthalmic solutions. Optometry 75(3):161-168 (2004) (Abstract only).	<input type="checkbox"/>
	012	GETTINGS et al. A comparison of low volume, Draize and in vitro eye irritation test data. III. Surfactant-based formulations. Food Chem Toxicol 36(3):209-231 (1998).	<input type="checkbox"/>
	013	GLASOE et al. Use of glass electrodes to measure acidities in deuterium oxide. Journal of Physical Chemistry. 64:188-190 (1960).	<input type="checkbox"/>
	014	Guidance for Industry: Q1A (R2) Stability Testing of New Drug Substances and Products. U.S. Department of Health and Human Services, Food and Drug Administration. Retrieved from the internet <a href="http://fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guideances/ucm073369.pdf">http://fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guideances/ucm073369.pdf</a> (25 pgs.) (November 2013/retrieved 7/27/2016).	<input type="checkbox"/>
	015	HUI et al. In vitro release of two anti-muscarinic drugs from soft contact lenses. Clin Ophthalmol 11:1657-1665 (2017).	<input type="checkbox"/>
	016	JANUSCHOWSKI et al. Evaluating retinal toxicity of a new heavy intraocular dye, using a model of perfused and isolated retinal cultures of bovine and human origins. Graefes Arch Clin Exp Ophthalmol. 250:1013-1022 (2012).	<input type="checkbox"/>
	017	JEONG et al. Biodegradable block copolymers as injectable drug-delivery systems. Nature 388(6645):860-862 (1997).	<input type="checkbox"/>
	018	JEONG et al. Drug release from biodegradable injectable thermosensitive hydrogel of PEG-PLGA-PEG triblock copolymers. J Control Release 63(1-2):155-163 (2000).	<input type="checkbox"/>
	019	JEONG et al. Thermosensitive sol-gel reversible hydrogels. Advanced Drug Delivery Reviews 54:37-51 (2002).	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**  
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Substitute for form 1449/PTO  <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(Use as many sheets as necessary)</p>				<b>Complete if Known</b>	
				Application Number	16805612
				Filing Date	02-28-2020
				First Named Inventor	OSTROW; Gregory I.
				Art Unit	
				Examiner Name	Not yet assigned
				Attorney Docket Number	46682-702.301
Sheet	9	of	11		

### NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author(in CAPITAL LETTERS), title of the article(when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	020	KREZEL et al. A formula for correlating pKa values determined in D2O and H2O. Journal of Inorganic Chemistry 98:161-166 (2008).	<input type="checkbox"/>
	021	KRUMBIEGEL. Large deuterium isotope effects and their use: a historical review. Isotopes in Environmental and Health Studies 47(1):1-17 (2011).	<input type="checkbox"/>
	022	LAI et al. Rapid transport of large polymeric nanoparticles in fresh undiluted human mucus. PNAS USA 104(5):1482-1487 (2007).	<input type="checkbox"/>
	023	LUND et al. The Kinetics of atropine and apoatropine in aqueous solutions. ACTA Chemica Scandinavica 22:3085-3097 (1968).	<input type="checkbox"/>
	024	MCCALL et al. Mechanisms of corneal tissue cross-linking in response to treatment with topical riboflavin and long-wavelength ultraviolet radiation (UVA). Investigative Ophthalmology & Visual Science 51(1):129-138 (2010).	<input type="checkbox"/>
	025	NEE. The Use Of Deuterium Oxide To Stabilize Pharmaceuticals Against Chemical Degradation. SlideServe - Theophilus Stavros. Retrieved from the Internet: URL: <a href="https://www.slideserve.com/theophilus-stavros/the-use-of-deuterium-oxide-to-stabilize-pharmaceuticals-against-chemical-degradation">https://www.slideserve.com/theophilus-stavros/the-use-of-deuterium-oxide-to-stabilize-pharmaceuticals-against-chemical-degradation</a> (20 pgs) (11/1/2014).	<input type="checkbox"/>
	026	OBATA et al. Deuterium magnetic resonance imaging of rabbit eye in Vivo. Magnetic Resonance in Medicine. 33(4):569-572 (1995).	<input type="checkbox"/>
	027	OBATA et al. Deuterium MR in vivo imaging of the rat eye using 2H2O. Acta Radiologica, 36:552-555 (1995).	<input type="checkbox"/>
	028	PCT/US2015/037249 International Search Report and Written Opinion dated September 30, 2015.	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**  
*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		Application Number	16805612
		Filing Date	02-28-2020
		First Named Inventor	OSTROW; Gregory I.
		Art Unit	
		Examiner Name	Not yet assigned
		Attorney Docket Number	46682-702.301
Sheet	10	of	11

## NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author(in CAPITAL LETTERS), title of the article(when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	029	PCT/US2016/029222 International Search Report and Written Opinion dated October 21, 2016.	<input type="checkbox"/>
	030	PCT/US2016/34823 International Search Report and Written Opinion dated August 23, 2016.	<input type="checkbox"/>
	031	RICHARD et al. Effects of sterilizing-grade filters on the physico-chemical properties of onion-like vesicles. Int J Pharm 312(1-2):144-150 (2006).	<input type="checkbox"/>
	032	SADEGHI-HASHJIN et al. Effects of Selected Antimuscarinic Agents on the Intra-Ocular Pressure in Healthy Rabbits. Journal of Pharmacology and Toxicology 3(5):382-385 (2008).	<input type="checkbox"/>
	033	SIEGEL et al. Stability of procaine in deuterium oxide. J Pharm Sci 53:978-979 (1964).	<input type="checkbox"/>
	034	SUSINA et al. Effect of Deuterium Oxide on Local Anesthetic Activity of Procaine. J Pharm Sci 51:1166-1169 (1962).	<input type="checkbox"/>
	035	TAKTAK et al. Assay of Pyrogens by Interleukin-6 Release from Monocytic Cell Lines. J. Pharm. Pharmacol. 43:578-582 (1991).	<input type="checkbox"/>
	036	The U. S. Food and Drug Administration has provided regulatory guidance in the publication: Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing. available at: <a href="http://www.fda.gov/cder/guidance/5882fn1.htm">http://www.fda.gov/cder/guidance/5882fn1.htm</a> (August 2003) (63 pgs.).	<input type="checkbox"/>
	037	U.S. Serial No. 14/859,042 Office Action dated May 18, 2017.	<input type="checkbox"/>
	038	U.S. Serial No. 14/859,042 Office Action dated October 25, 2016.	<input type="checkbox"/>
	039	U.S. Serial No. 15/208,537 Office Action dated January 25, 2017.	<input type="checkbox"/>
	040	U.S. Serial No. 15/208,537 Office Action dated September 30, 2016.	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	16805612		
		Filing Date	02-28-2020		
		First Named Inventor	OSTROW; Gregory I.		
		Art Unit			
		Examiner Name	Not yet assigned		
Sheet	11	of	11	Attorney Docket Number	46682-702.301

### NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author(in CAPITAL LETTERS),title of the article(when appropriate), title of the item (book,magazine,journal,serial,symposium,catalog,etc.),date,page(s),volume-issue number(s),publisher, city and/or country where published.	T <sup>2</sup>
	041	U.S. Serial No. 15/568,381 Office Action dated April 3, 2019.	<input type="checkbox"/>
	042	U.S. Serial No. 15/568,381 Office Action dated November 22, 2019.	<input type="checkbox"/>
	043	U.S. Serial No. 15/578,202 Office Action dated January 3, 2020.	<input type="checkbox"/>
	044	U.S. Serial No. 15/578,202 Office Action dated June 28, 2019.	<input type="checkbox"/>
	045	U.S. Serial No. 15/661,816 Office Action dated November 24, 2017.	<input type="checkbox"/>
	046	U.S. Serial No. 15/895,933 Office Action dated August 9, 2018.	<input type="checkbox"/>
	047	U.S. Serial No. 16/224,286 Office Action dated December 23, 2019.	<input type="checkbox"/>
	048	U.S. Serial No. 16/677,538 Office Action dated January 13, 2020.	<input type="checkbox"/>
	049	VIEGAS et al. Osmotic behavior of poloxamer 407 and other non-ionic surfactants in aqueous solutions. Int J Pharm 160:157-162 (1998).	<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*