CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-775/S001

ADMINISTRATIVE DOCUMENTS

EXCLUSIVITY SUMMARY for NDA # 50-775 SUPPL # S-001

Trade Name: Biaxin XL Tablets Generic Name: clarithromycin

Applicant Name: Abbott HFD- 520

Approval Date: August 2, 2001

PART I: IS AN EXCLUSIVITY DETERMINATION NEEDED?

This drug was previously approved under section 507.

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete Parts II and III of this Exclusivity Summary only if you answer "YES" to one or more of the following questions about the submission.

   a) Is it an original NDA? YES/___/ NO /___/

   b) Is it an effectiveness supplement? YES /___/ NO /___/

      If yes, what type(SE1, SE2, etc.)? _____

   c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "NO.")

      YES /___/ NO /___/

      If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

      _____

      _____

      If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

      _____

d) Did the applicant request exclusivity?

YES /___/ NO /___/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety?

YES /___/ NO /___/

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use? (Rx to OTC Switches should be answered No - Please indicate as such).

YES /___/ NO /___/

If yes, NDA # _____ Drug Name _____

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /___/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9 (even if a study was required for the upgrade).

PART II: FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2, as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # _____ _____

NDA # _____ _____

NDA # _____ _____

2. Combination product.

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # _____ _____

NDA # _____ _____

NDA # _____ _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9. IF "YES," GO TO PART III.

PART III: <u>THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS</u>

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2, was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

   YES /___/ NO /___/

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis

for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

For the purposes of this section, studies comparing two products with the same ingredient(s) are considered to be bioavailability studies.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES /___/ NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval **AND GO DIRECTLY TO SIGNATURE BLOCK ON Page 9:**

_____

_____

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /___/ NO /___/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO /___/

If yes, explain: _____

_____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO /___/

If yes, explain: _____

_____

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Investigation #1, Study # _____

Investigation #2, Study # _____

Investigation #3, Study # _____

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

(a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

Investigation #3 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

NDA # _____ Study # _____
NDA # _____ Study # _____
NDA # _____ Study # _____

(b) For each investigation identified as "essential to the approval," does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES /___/ NO /___/

Investigation #2 YES /___/ NO /___/

Investigation #3 YES /___/ NO /___/

If you have answered "yes" for one or more investigations, identify the NDA in which a similar investigation was relied on:

NDA # _____ Study # _____

NDA # _____ Study # _____

NDA # _____ Study # _____

(c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Investigation #__, Study # _____

Investigation #__, Study # _____

Investigation #__, Study # _____

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

(a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1

IND # _____ YES /___/ ! NO /___/ Explain: _____

! _____

! _____

Investigation #2

IND # _____ YES /___/ ! NO /___/ Explain: _____

! _____

! _____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1

YES /___/ Explain _____ ! NO /___/ Explain _____

_____ ! _____

_____ ! _____

Investigation #2

YES /___/ Explain _____ ! NO /___/ Explain _____

_____ ! _____

_____ ! _____

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /___/

If yes, explain: _____

_____

_____

/S/ 7/31/2001

Signature of Preparer Date

Title: Project Manager

/S/ 8/2/01

Signature of Office or Division Director Date

cc:
Archival NDA
HFD- /Division File
HFD- /RPM
HFD-093/Mary Ann Holovac
HFD-104/PEDS/T.Crescenzi

Form OGD-011347
Revised 8/7/95; edited 8/8/95; revised 8/25/98, edited 3/6/00

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA Number: N 050775
Trade Name: BIAXIN XL FILMTAB(CLARITHROMYCIN)500MG E
Generic Name: CLARITHROMYCIN
Supplement Number: 001 **Supplement Type**: SE1
Dosage Form:
Regulatory Action: AP **Action Date**: 8/2/01
COMIS Indication: ANTIBIOTIC

Indication #1: THE PURPOSE OF THIS SUPPLEMENT IS TO ADD: "PNEUMONIA DUE TO HAEMOPHILUS INFLUENZA, HAEMOPHILUS PARAINFLUENZAE, MORAXELLA CATARRHALIS, STAPHYLOCOCCUS AUREUS, STREPTOCOCCUS PNEMONIAE, CHLAMYDIA PNUEMONIAE, LEGIONELLA PNEUMOPHILA. MYCOPLAS.PNEU
Label Adequacy: Adequate for some pediatric age groups
Formulation Needed: No new formulation is needed
Comments (if any) The approved pediatric dosage form of clarithromycin (Biaxin Granules) is already labeled for CAP, and the dose and tablet size of the BIAXIN XL dosage form (500 mg) is too large to be acceptable for use in young children. BIAXIN XL 500 mg is an alternative dosage form for children 12 years old and older.

Lower Range	Upper Range	Status	Date
12 years	Adult	Waived	3/3/00

Comments: Abbott has documented attempts to develop a pediatric extended released formulation.
See waiver request August 4, 1999.

This page was last edited on 8/27/01

/S/ 8/27/01

Signature Date

Certification Requirement
For Approval of a Drug Product
Concerning Using Services of Debarred Persons

- DEBARMENT STATEMENT -

Any application for approval of a new drug product submitted on or after June 1, 1992, per FD&C Act Section 306 (k)(1), must include:

> (1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under Section 306, subsection (a) or (b), in connection with such application.

Abbott Laboratories certifies that it did not and will not use in any capacity the services of any person debarred under Section 306, subsection (a) or (b), in connection with such application.

[Generic Drug Enforcement Act of 1992, Section 306(k)(1) of 21 USC 335a(k)(1)].

Greg Bosco 9/28/00

Greg Bosco
Sr. Product Manager, PPD Regulatory Affairs
Abbott Laboratories
Dept. 491, Bldg. AP6B-1
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100 Abbott Park Road
Abbott Park, Illinois 60064-6108

BIAXIN® (clarithromycin tablets)
NDA 50-775, S-001

REQUEST FOR WAIVER
OF PEDIATRIC STUDY REQUIREMENT

In accordance with the provisions of 21 CFR 314.55(c)(2) Abbott Laboratories is requesting a full waiver of the pediatric study requirement. This request is based on the premise that the drug product does not represent a meaningful therapeutic benefit over existing treatments for pediatric patients and is not likely to be used in a substantial number of pediatric patients for the following reasons:

Background

Commercially available Biaxin Tablets, NDA 50-662 (approved 10/31/91), is an immediate-release, coated 250 mg and 500 mg tablet product consisting of an [redacted] Commercially available Biaxin Granules, NDA 50-698 (approved 8/12/94), is a dry granule product which after constitution results in a suspension containing 125 mg, 187.5 mg or 250 mg of clarithromycin activity per [redacted] Biaxin Granules are small coated particles which consist of clarithromycin and excipients coated with a [redacted] when compared to the clarithromycin tablet. [redacted]

To meet a need for an extended-release tablet formulation, Biaxin XL Tablets were developed. Biaxin XL Tablets, NDA 50-775 (approved 3/3/00), are extended-release-500 mg tablets consisting of a [redacted] which delivers 500 mg of clarithromycin at an extended rate. Proposed labeling for Biaxin XL Tablets (NDA 50-775, S-001) includes dosing q24h for community-acquired pneumonia.

Justification

1. The indication studied in this supplement (NDA 50-775, S-001), is community-acquired pneumonia. While this disease affects patients of all age groups, this particular dosage form (Biaxin XL Tablets) does not represent a meaningful therapeutic benefit over existing treatments for pediatric patients for the following reasons. First, the dose and tablet size of the Biaxin XL dosage form (500 mg) is quite large and would not be acceptable for use in young children. Second, the studies submitted in this NDA for community-acquired pneumonia had as an inclusion criteria "that patients be at least 18 years of age". This inclusion criteria was chosen due to the class of comparators chosen (quinolones) which have Warnings and Precautions statements in their package inserts that prohibit their use in pediatric patients because the safety and efficacy of the comparators in adolescents (under the age of 18 years) have not been established.

   For pediatric patients the currently approved pediatric dosage form of clarithromycin (Biaxin Granules), which is indicated for community-acquired pneumonia, is commercially available.

2. Development of a pediatric extended-release formulation has been explored by Abbott Laboratories. Six prototype formulations were developed and tested in pilot, multiple-dose biostudies vs. the marketed immediate-release formulation (Biaxin Granules). All prototype formulations resulted in pharmacokinetic performance with regard to 24-hour AUC and Cmin that was unacceptable. We believe that these results could be related to clarithromycin's acid instability or its potential metabolism by CYP3A in the duodenum.

The coating which is applied to the current Biaxin Granules formulation may offer at least partial protection against acid in the stomach and/or metabolism in the small intestine. The challenge from an extended-release pediatric product development standpoint has been to combine the appropriate protective coating with the small granule size necessary for an acceptable suspension and still achieve the desired extent of absorption. From a U.S. regulatory position, none of the prototypes would be acceptable from an FDA approval standpoint as none of them achieved an AUC which approached that of the immediate-release formulation (Biaxin Granules). As a result, no further development of an extended-release pediatric dosage form for possible marketing in the U.S. is being pursued.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: 3/31/02

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☑ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	See Attached List	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Lawrence E Roebel, Ph.D.	Vice President, PPD Regulatory Affairs and Research Quality Assurance
FIRM/ORGANIZATION	
Abbott Laboratories	
SIGNATURE	**DATE**
Greg Bruce for L.E. Roebel	9/29/00

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
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BIAXIN XL
STUDY NO. M99-077
FINANCIAL DISCLOSURE
"CERTIFICATION"

CLINICAL INVSTIGATORS		
Acampora, Mathew D.		
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Bebawy, Sam T.		
Yong Choo		
Adrian Pristas		
Behm, John L.		
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Kurt Heil	Keith Reisinger	Kimberly Sprenkle
Charity Istone	Toni Scanlan	
Berman, Steven J.		
Heidi Berman	E. Wilson Johnson	
Jane Doll	Eugene Wong	
Bettis, Robert		
Paul Bagnulo	Mark Hanson	Martin Proudfoot
Martha Bennett	Teresa Hildebrand	Susanne Quistgaard
Ginger Blakeney	Myra Horiuchi	Jeff Schlameus
Sandra Borg	Laura Lippman	Jae Sim
Ross Carey	Rocky Mazzeo	David Taibleson
Robin Colbath	Donald Moe	Donald Tesch
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Karol Davis	Jennifer Peterson	Daniel Weakly
Victoria Fields-Vocelka	Joseph Petrin	
Blumberg, Michael		
Barry Feinstein	Mary Lou Hayden	Jeffrey Schul
Bray, Elizabeth S.		
Kecia Barrack	Kathryn McKinney	Zandra Petway
Sally Bullock	Utpal Patel	Kim Shannon
Terry Deason		
Bundy, John M.		
Evette Budrich	Debra Riggs	Kent Studebaker
Ted Fortman	Billy Sipes	

Note: **Principal Investigator is bolded**

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Mehul Patel*	Beverly Reynolds*	
*FDCs filed in M. Patels documents		
Chittom, Park II		
Daniel Clower	Park Chittom	
Claassen, David		
Scott Charlton	Allison Gomillion	Sherri Senn
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Carol Gilmer		
Cone, Clancy		
Thomas Bell	Kelly Etzel	Jennifer Krueger
Coyle, Stephen J.		
J. D. Fox	A. G. Jowett	Louis Pierre Leung Shing
Duane Hartley	Edward Lawrence	J. R. A. Stuart
Cutler, Michael		
Elwood Corry	Ruth Hooper	Terrell Thompson
Glen Fuller	Scott Smith	Marshall Willis, Jr.
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Richard Conroy	Debra Kerr	Shaukat Matin
Dattani, Daniel		
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Deutsch, Raymond M.		
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William Granillo	Kuldip Thusu	
Dietrich, Robert A.		
John Fogarty	Phillip Perkins	
Richard Mann	Robert Shaw	
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Note: **Principal Investigator is bolded**

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Garrity, Joseph G.		
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Gohill, Vina B.		
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Guzzetta, Richard V.		
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Note: **Principal Investigator is bolded**

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Tammy O'Dell	Teri Salyer	Nicholas Timm
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Deborah Massetti	Kevin Wingert	
Jessica Stendel		
Jones, Robert F.		
Kirk Jacobson		
Kraig Jacobson		
Kutner, Mark E.		
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Dale Matza	Eric Smith	
Lawlor, Dennis		
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Michelle Drummond	Everett Murphy	Jeanne Zirkle
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Marisa Neis-Gimenez		
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McConnehey, Diane O.		
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Brock McConnehey		
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Christine Hutchins	Cynthia Partain	
M. Dean McLaughlin	Brian Way	
McNeil, Daniel L.		
Steve Bazer		

Note: **Principal Investigator is bolded**

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CLINICAL INVSTIGATORS		
Miller, David J.		
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Maureen Daniels	Patricia McMichael	
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Patel, Mehul		
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Deb Mielke		
Pien, Francis		
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Syed Akbarullah	Ivan Goldsmith	Robert Pretto
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William Boren	Russell Neibaur	Marvin Willard
Luke Cesaretti	Nawaz Qureshi	Betty Yao
Pogue, Bryan C.		
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Kathryn Colson	Jami Klimek	Greg Valceschini
Raad, George		
Devorah Werner*		
*FDCs filed in M. Acampora's documents		
Riffer, Ernie		
Barbara Berry		
Barbara Lipschitz		

Note: Principal Investigator is bolded

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Lynn Reilly		
Shu, Daniel		
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Smith, Thomas P.		
Dean Kirby		
Sokol, Jr., William N.		
Anthony Horner		
Stotler, Charles W.		
Dawn Horner	John Onderko	Denise Schmitt
Carol Miller	Cheryl Rosenberg	Maureen Yadlosky
Stewart, George L.		
Beth Baker	Gregory Gerboth	Kwie-Hoa Siem
Suchyta, Mary R.		
W. Derek Boam	Carla Foster	Alan Naylor
Thomas Boud	Daniel Hartmann	Kevin O'Meara
Chad Christensen	Brenda Johnson	Nathan Schafer
John Crites	Georger Joseph	Alan Whitesides
Richard Crockett		
Sullivan, James G.		
Andreas Maddux		
Gregory Flippo		
Tarshis, Gary A.		
Avrim Cantor	Susan Stone	
Mark Fraley	Mark Walton	
Villanueva, Jesus E.		
Jose Armonio		
John Rathbun		
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