

**CENTER FOR DRUG EVALUATION AND RESEARCH  
KEY OFFICIALS**

**July 23, 2009**

**OFFICE OF THE CENTER DIRECTOR (OCD)**

**DIRECTOR**

|  |              |                |
|--|--------------|----------------|
| <b>Janet Woodcock, M.D.</b>  | 301-796-5400 | W O51/Rm. 6133 |
| Executive Assistant<br>Dannette Alpern   | 301-796-5400 | W O51/Rm. 6131 |
| Deputy Director<br>Douglas C. Throckmorton, M.D.   | 301-796-5400 | W O51/Rm. 6132 |
| Program Support Specialist<br>Jancie Shelton   | 301-796-5400 | W O51/Rm. 6128 |
| Associate Director for Planning<br>and Business Informatics<br>Theresa Mullin, Ph.D.         | 301-796-3422 | W O51/Rm. 6122 |
| Office Automation Assistance<br>Kathleen Smith   | 301-796-5400 | W O51/Rm. 6145 |
| Associate Director for Safety Policy<br>and Communication<br>Steven Osborne (Actg), M.D.     | 301-796-5401 | W O51/Rm. 5154 |
| Project Specialist<br>Gala Abraham   | 301-796-3513 | W O51/Rm. 5157 |
| Drug Safety Oversight Board<br>Steven Osborne, M.D.  | 301-796-3604 | W O51/Rm. 5158 |
| Project Specialist<br>Georgiann lenzi  | 301-796-3515 | W O51/Rm. 5159 |
| Associate Director for Medical Informatics<br>Randy Levin, M.D.                      HFD-001 | 301-827-7784 | PKLN/Rm. 14B45 |
| Associate Director for International Program<br>Justina A. Molzon, J.D.                      | 301-796-5400 | W O51/Rm. 6118 |
| Ombudsman<br>Virginia Behr   | 301-796-3436 | W O51/Rm. 6158 |
| Controlled Substance Staff<br>Michael Klein, Ph.D. (Actg.)                                   | 301-796-3119 | W O51/Rm. 5142 |

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| Senior Management Officer<br>Amy Garvin (Actg.) | 301-796-3413 | W O51/Rm. 6106 |
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#### **OFFICE OF PHARMACEUTICAL SCIENCE (OPS)**

|                          |              |                 |
|--------------------------|--------------|-----------------|
| Director<br>Helen Winkle | 301-796-2400 | W O 51/Rm. 4184 |
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| Technical Information Specialist<br>Vera Viehmann | 301-796-1622 | W O 51/Rm. 4183 |
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| Deputy Director<br>Keith Webber, Ph.D. | 301-796-2400 | W O 51/Rm. 4192 |
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| Director, Program Activities Review Staff<br>Jon Clark | 301-796-1518 | W O 51/Rm. 4178 |
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| Director, Operations Staff<br>Christopher Cole, MPA | 301-796-1521 | W O 51/Rm. 4196 |
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| Director, Science and Research Staff<br>Nakissa Sadrieh, Ph.D. | 301-796-1598 | W O 51/Rm. 4172 |
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| Director, New Drug Microbiology Staff<br>David Hussong, Ph.D. | 301-796-1228 | W O 51/Rm. 4166 |
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#### **OFFICE OF BIOTECHNOLOGY PRODUCTS (OBP)**

|                                    |              |                 |
|------------------------------------|--------------|-----------------|
| Director<br>Steven Kozlowski, M.D. | 301-796-2390 | W O 21/Rm. 1510 |
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| Deputy Director<br>Vacant | 301-796-2390 | W O 21/Rm. 1506 |
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| Management Officer<br>James Selby, Jr. | 301-796-1774 | W O 21/Rm. 1516 |
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#### **Division of Monoclonal Antibodies (DMA)**

|                                    |         |              |                   |
|------------------------------------|---------|--------------|-------------------|
| Director<br>Kathleen Clouse, Ph.D. | HFD-123 | 301-827-0850 | NIH 29B RM. 4NN12 |
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| Deputy Director<br>Patrick Swann, Ph.D. | HFD-123 | 301-827-0850 | NIH 29B RM. 3NN10 |
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#### **Division of Therapeutic Proteins (DTP)**

|                                 |         |              |               |
|---------------------------------|---------|--------------|---------------|
| Director<br>Amy Rosenberg, M.D. | HFD-122 | 301-827-1790 | N29A/Rm. 2D16 |
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Deputy Director

|                      |         |              |               |
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| Barry Cherney, Ph.D. | HFD-122 | 301-827-1790 | N29A/Rm. 2D16 |
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**OFFICE OF TESTING AND RESEARCH (OTR)**

|                                   |  |              |                 |
|-----------------------------------|--|--------------|-----------------|
| Director<br>Vincent Vilker, Ph.D. |  | 301-796-0200 | W O 22/Rm. 2130 |
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| Deputy Director<br>Vacant |  |  |  |
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| Management Officer<br>Charis Miller |  | 301-796-0202 | W O 22/Rm. 2128 |
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**Laboratory of Clinical Pharmacology (LCP)**

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| Director<br>Robert Parker, Ph.D. (Actg.) |  | 301-796-0117 | W O 64/Rm. 2067 |
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**Division of Applied Pharmacology Research (DAPR)**

|   |  |              |                 |
|---|--|--------------|-----------------|
| Director<br>Vincent Vilker, Ph.D. (Actg.) |  | 301-796-0200 | W O 22/Rm. 2130 |
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| Deputy Director<br>Joseph Hanig, Ph.D. |  | 301-796-0079 | W O 64/Rm. 2076 |
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**Division of Product Quality Research (DPQR)**

|                                 |  |              |                 |
|---------------------------------|--|--------------|-----------------|
| Director<br>Mansoor Khan, Ph.D. |  | 301-796-0016 | W O 64/Rm. 1006 |
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| Deputy Director<br>Robbe Lyon, Ph.D. |  | 301-796-0019 | W O 64/Rm. 1008 |
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**Division of Pharmaceutical Analysis (DPA)**

|                                     |         |              |   |
|-------------------------------------|---------|--------------|---|
| Director<br>Lucinda F. Buhse, Ph.D. | HFD-920 | 314-539-2134 | 1114 Market St.<br>Rm 1002<br>St. Louis, MO 63101 |
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| Deputy Director<br>Benjamin Westenberger | HFD-920 | 314-539-3869 | 1114 Market St.<br>Rm. 1002<br>St. Louis, MO 63101 |
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**OFFICE OF GENERIC DRUGS (OGD)**

|                                     |         |              |               |
|-------------------------------------|---------|--------------|---------------|
| Director<br>Gary J. Buehler, R. Ph. | HFD-600 | 240-276-9310 | MPN4/Rm. 3020 |
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Technical Information Specialist

|   |         |              |                |
|---|---------|--------------|----------------|
| Patricia Downs  | HFD-600 | 240-276-9310 | MPN4/Rm. 3010  |
| Deputy Director<br>Robert West, R.Ph.   | HFD-601 | 240-276-9310 | MPN 2/Rm. E283 |
| Director for Science<br>Lawrence Yu, Ph.D.                                    | HFD-600 | 240-276-9310 | MPN4 /Rm. 3014 |
| Associate Director for Medical Affairs<br>Dena Hixon, M.D.                    | HFD-600 | 240-276-9310 | MPN2/Rm. 2210  |
| Associate Director for Chemistry<br>Frank O. Holcombe, Jr., Ph.D.             | HFD-600 | 240-276-9310 | MPN2/Rm. N131  |
| Associate Director for Operations<br>and Communications<br>Rita Hassall, R.N. | HFD-600 | 240-276-9310 | MPN4/Rm. 3019  |
| Management Officer<br>Patricia Littleton                                      | HFD-600 | 240-276-9322 | MPN4/Rm. 3024  |

#### **Division of Chemistry I (DCI)**

|   |         |              |               |
|---|---------|--------------|---------------|
| Director<br>Rashmikant Patel, Ph.D.     | HFD-620 | 240-276-8500 | MPN2/Rm. E203 |
| Deputy Director<br>Paul Schwartz, Ph.D. | HFD-621 | 240-276-8500 | MPN2/Rm. 206  |

#### **Division of Chemistry II (DCII)**

|   |         |              |               |
|---|---------|--------------|---------------|
| Director<br>Florence Fang, Ph.D.        | HFD-640 | 240-276-8505 | MPN2/Rm. E270 |
| Deputy Director<br>Richard Adams, Ph.D. | HFD-640 | 240-276-8505 | MPN2/Rm. E270 |

#### **Division of Chemistry III (DCIII)**

|                                   |         |              |               |
|-----------------------------------|---------|--------------|---------------|
| Director<br>Vilayat Sayeed, Ph.D. | HFD-630 | 240-276-8444 | MPN2/Rm. E133 |
| Deputy Director<br>Devinder Gill  | HFD-630 | 240-276-8444 | MPN2/Rm E134  |

#### **Division of Bioequivalence (DB)**

|                                   |         |              |               |
|-----------------------------------|---------|--------------|---------------|
| Director<br>Dale Conner, Pharm.D. | HFD-650 | 240-276-8782 | MPN1/Rm. 1341 |
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| Deputy Director<br>Barbara Davit, Ph.D. | HFD-651 | 240-276-8782 | MPN1/Rm. 1343 |
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### **Division of Labeling and Program Support (DLPS)**

|                           |         |              |               |
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| Director<br>Peter Rickman | HFD-610 | 240-276-8400 | MPN2/Rm. N129 |
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Deputy Director  
Vacant

### **OFFICE OF NEW DRUG QUALITY ASSESMENT (ONDQA)**

|                               |  |              |                |
|-------------------------------|--|--------------|----------------|
| Director<br>Moheb Nasr, Ph.D. |  | 301-796-1900 | W O 21/Rm 2630 |
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| Program Support Specialist<br>Patricia O'Connor |  | 301-796-1727 | W O 21/Rm 2691 |
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| Deputy Director<br>Christine Moore, Ph.D. (Actg-Detail-120 days) |  | 301-796-1900 | W O 21/Rm 2626 |
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| Management Officer<br>Shanell Owens (Actg) |  | 301-796-1729 | WO 21/Rm 2677 |
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### **Division of Pre-Marketing Assessment I (DPA I)**

|  |  |              |                |
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| Director<br>Christine Moore, Ph.D. (Actg.) |  | 301-796-2410 | W O 21/Rm 2526 |
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| Branch Chief<br>Ramesh Sood, Ph.D. |  | 301-796-1466 | W O 21/Rm 2530 |
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| Branch Chief, Ph.D.<br>Ali Al-Hakim |  | 301-796-1323 | W O 21/Rm 2524 |
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### **Division of Pre-Marketing Assessment II (DPA II)**

|                                     |  |              |                |
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| Director<br>Elaine Morefield, Ph.D. |  | 301-796-2420 | W O 22/Rm 2474 |
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| Branch Chief<br>Norman Schmuff, Ph.D. |  | 301-796-1454 | W O 22/Rm 2472 |
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| Branch Chief<br>Moo Jhong Rhee |  | 301-796-1440 | W O 22/Rm 2486 |
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## **Division of Pre-Marketing Assessment III & Manufacturing Science (DPAMS)**

|  |              |                |
|--|--------------|----------------|
| Director<br>Richard Lostritto, Ph.D.                     | 301-796-2430 | W O 22/Rm 2416 |
| Branch Chief<br>Ravi Harapanhalli, Ph.D                  | 301-796-1676 | W O 22/Rm 2414 |
| Branch Chief<br>Christine Moore, Ph.D. (Detail-120 days) | 301-796-1422 | W O 22/Rm 2418 |

## **Division of Post-Marketing Evaluation (DPE)**

|                                      |              |                |
|--------------------------------------|--------------|----------------|
| Director<br>Eric Duffy, Ph.D.        | 301-796-2440 | W O 21/Rm 2614 |
| Branch Chief<br>James Vidra, Ph.D.   | 301-796-1767 | W O 21/Rm 2620 |
| Branch Chief<br>Hasmukh Patel, Ph.D. | 301-796-2440 | W O 21/Rm 2616 |

## **OFFICE OF REGULATORY POLICY (ORP)**

|                                       |              |                 |
|---------------------------------------|--------------|-----------------|
| Director<br>Jane A. Axelrad, J.D.     | 301-796-5400 | W O 51/Rm. 6140 |
| Special Assistant<br>Michael D. Jones | 301-796-3602 | W O 51/Rm. 6216 |
| Management Officer<br>Amy Garvin      | 301-796-3413 | W O 51/Rm. 6106 |

## **Division of Regulatory Policy I (DRPI)**

|                                 |              |                 |
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| Director<br>Nancy Boocker, J.D. | 301-796-3601 | W O 51/Rm. 6244 |
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## **Division of Regulatory Policy II (DRPII)**

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| Director<br>Michael Bernstein, J.D. | 301-796-3602 | W O 51/Rm. 6240 |
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## **Division of Information Disclosure Policy (DIDP)**

|                         |              |                 |
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| Director<br>Nancy Sager | 301-796-3603 | W O 51/Rm. 6264 |
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## **OFFICE OF EXECUTIVE PROGRAMS (OEP)**

|  |         |              |                 |
|--|---------|--------------|-----------------|
| Director<br>Deborah Henderson                          |         | 301-796-1446 | W O 51/Rm. 6148 |
| Deputy Director<br>Jayne Ware                          |         | 301-796-3433 | W O 51/Rm. 6152 |
| Director's Secretary<br>Tracy Porter                   |         | 301-796-3419 | W O 51/Rm. 6115 |
| Executive Operations Staff<br>Christine Bechtel        |         | 301-796-3449 | W O 51/Rm. 6186 |
| Team Leader Program Management Team<br>Jamie Metz      |         | 301-796-3417 | W O 51/Rm. 6112 |
| Quality Management Staff<br>Lana Pauls                 |         | 301-796-0518 | W O 51/Rm. 6196 |
| Advisors and Consultants Staff<br>Igor Cerny, Pharm.D. | HFD-021 | 301-827-6763 | FHSL/Rm. 1088   |
| Management Officer<br>Amy Garvin                       |         | 301-796-3413 | W O 51/Rm. 6106 |

#### **OFFICE OF MANAGEMENT (OM)**

|  |         |              |                 |
|--|---------|--------------|-----------------|
| Director<br>Russell J. Abbott            |         | 301-796-3300 | W O51//Rm. 5135 |
| Secretary<br>Tiffany Crawford            |         | 301-796-3300 | W O51//Rm. 5135 |
| Deputy Director<br>Robert Linkous        |         | 301-796-3300 | W O51//Rm. 5135 |
| Management Officer<br>Rebecca E. Glidden | HFD-060 | 301-827-0894 | MM2/Rm. 305     |

#### **Division of Management and Budget (DMB)**

|  |         |              |              |
|--|---------|--------------|--------------|
| Director<br>Rixie Scott                                | HFD-050 | 301-827-0933 | MM2/Rm. 306  |
| Planning and Resource Management Branch<br>Katie Green | HFD-050 | 301-827-1270 | MM2I/Rm. 307 |
| Management Analysis Branch<br>Don Kim                  | HFD-050 | 301-827-1467 | MM2/Rm. 309  |

## **Division of Management Services (DMS)**

|  |         |              |             |
|--|---------|--------------|-------------|
| Director<br>Mary Milline                               | HFD-060 | 301-827-2475 | MM2/Rm. 340 |
| Deputy Director<br>Tania Tse                           | HFD-060 | 301-827-2478 | MM2/Rm. 342 |
| Program Management Services Branch<br>Patricia Gathers | HFD-065 | 301-827-2466 | MM2/Rm. 333 |
| Interface Management Branch<br>Stephanie Hawk          | HFD-067 | 301-827-2511 | MM2/Rm. 347 |

## **OFFICE OF NEW DRUGS (OND)**

|  |  |              |                 |
|--|--|--------------|-----------------|
| Director<br>John Jenkins, M.D.   |  | 301-796-0700 | W O 22/Rm. 6304 |
| Program Support Specialist<br>Patreese Morton  |  | 301-796-0173 | W O 22/Rm. 6301 |
| Deputy Director<br>Sandra Kweder, M.D.   |  | 301-796-0700 | W O 22/Rm. 6306 |
| Senior Management Officer<br>Eldridge Coles  |  | 301-796-0141 | W O 22/Rm. 6418 |
| Associate Director of Pharmacology<br>and Toxicology<br>David Jacobson-Kram, Ph.D., D.A.B.T. |  | 301-796-0175 | W O 22/Rm. 6488 |
| Associate Director for Regulatory Affairs<br>Kim Quaintance                                  |  | 301-796-0700 | W O 22/Rm. 6300 |
| Associate Director, Study Endpoints &<br>Labeling Development<br>Laurie Burke, R.Ph., M.P.H  |  | 301-796-0900 | W O 22/Rm. 6462 |
| Associate Director, Pediatrics &<br>Maternal Health Staff<br>Lisa Mathis, M.D.               |  | 301-796-2200 | W O 22/Rm. 6414 |
| Lead Medical Officer, Guidance/Policy Team<br>Sally Loewke, M.D.                             |  | 301-796-0700 | W O 22/Rm. 6312 |



## OFFICE OF DRUG EVALUATION I (ODEI)

Director  
Robert J. Temple, M.D. (Actg.) 301-796-2270 W O 22/Rm. 4217

Assistant  
Aprile Blount 301-796-2270 W O 22/Rm. 4217

Deputy Director  
Dr. Ellis Unger 301-796-2270 W O 22/Rm. 4217

Associate Director for Regulatory Affairs  
Colleen LoCicero 301-796-2270 W O 22/Rm. 4217

Management Officer  
Tammy Sauter (Actg.) 301-796-2270 W O 22/Rm. 4232

### **Division of Cardiovascular Renal Products (DCRP)**

Director  
Norman Stockbridge, M.D., Ph.D. 301-796-2240 W O 22/Rm. 4168

Deputy Director  
Ellis Unger, M.D. 301-796-2240 W O 22/Rm. 4170

Supervisory Project Manager  
Edward Fromm 301-796-2240 W O 22/Rm. 4162

### **Division of Neurology Products (DNP)**

Director  
Russell G. Katz, M.D. 301-796-2250 W O 22/Rm. 4332

Deputy Director  
Vacant

Supervisory Project Manager  
Robbin Nighswander, R.Ph. 301-796-2250 W O 22/Rm. 4346

### **Division of Psychiatry Products (DPP)**

Director  
Thomas Laughren, M.D. 301-796-2260 W O 22/Rm. 4114

Deputy Director  
Mitchell Mathis, M.D. 301-796-2260 W O 22/Rm. 4112

Supervisory Project Managers  
Steven Hardeman, R.Ph. 301-796-2260 W O 22/Rm. 4390  
Paul David, R.Ph. 301-796-2260 W O 22/Rm. 4100

## OFFICE OF DRUG EVALUATION II (ODEII)

|                                      |              |                 |
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| Director<br>Curtis Rosebraugh, M. D. | 301-796-2310 | W O 22/Rm. 3214 |
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| Secretary<br>Velma Cunningham | 301-796-2310 | W O 22/Rm. 3221 |
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| Deputy Director<br>Vacant | 301-796-2310 | W O 22/Rm 3210 |
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| Associate Director for Regulatory Affairs<br>Leah Ripper | 301-796-1282 | W O 22/Rm. 3218 |
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| Management Officer<br>Thomas Cunningham | 301-796-1196 | W O 22/Rm. 3208 |
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### **Division of Metabolism and Endocrinology Products (DMEP)**

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|------------------------------|--------------|-----------------|
| Director<br>Mary Parks, M.D. | 301-796-2290 | W O 22/Rm. 3362 |
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| Deputy Director<br>Eric Colman, M.D. | 301-796-1190 | W O 22/Rm. 3360 |
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| Supervisory Project Managers<br>Enid M. Galliers | 301-796-1211 | W O 22/Rm. 3356 |
| Lina Aljuburi                                    | 301-796-1168 | W O 22/Rm. 3366 |

### **Division of Pulmonary and Allergy Products (DPAP)**

|                                    |              |                 |
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| Director<br>Badrul Chowdhury, M.D. | 301-796-2300 | W O 22/Rm. 3316 |
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| Deputy Director<br>Vacant |  |  |
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| Supervisory Project Manager<br>Sandra L. Barnes | 301-796-1174 | W O 22/Rm. 3306 |
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### **Division of Analgesics, Anesthetics, and Rheumatology Products (DAARP)**

|                                    |              |                 |
|------------------------------------|--------------|-----------------|
| Director<br>Bob A. Rappaport, M.D. | 301-796-2280 | W O 22/Rm. 3168 |
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| Deputy Director<br>Sharon Hertz, M.D. | 301-796-2280 | W O 22/Rm. 3170 |
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| Deputy Director |  |  |
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| Rigoberto Roca, M.D.         | 301-796-2280 | W O 22/Rm. 3136 |
| Supervisory Project Managers |              |                 |
| Parinda Jani                 | 301-796-1232 | W O 22/Rm. 3166 |
| Sara Stradley                | 301-796-1298 | W O 22/Rm. 3162 |

**OFFICE OF DRUG EVALUATION III (ODEIII)**

|   |              |                 |
|---|--------------|-----------------|
| Director                                  |              |                 |
| Julie Beitz, M.D.                         | 301-796-2100 | W O 22/Rm. 5214 |
| Program Support Specialist                |              |                 |
| Diane Thomas                              | 301-796-0220 | W O 22/Rm. 5221 |
| Deputy Director                           |              |                 |
| Daniel Shames, M.D.                       | 301-796-2100 | W O 22/Rm. 5210 |
| Associate Director for Regulatory Affairs |              |                 |
| Bronwyn E. Collier                        | 301-796-2100 | W O 22/Rm. 5218 |
| Management Officer                        |              |                 |
| Antoinette Mason                          | 301-796-0954 | W O 22/Rm. 5206 |

**Division of Reproductive and Urologic Products (DRUP)**

|                              |              |                 |
|------------------------------|--------------|-----------------|
| Director                     |              |                 |
| Scott Monroe, M.D.           | 301-796-2130 | W O 22/Rm. 5380 |
| Deputy Director              |              |                 |
| George Benson, M.D.          | 301-796-2130 | W O 22/Rm. 5346 |
| Supervisory Project Managers |              |                 |
| Margaret Kober               | 301-796-2130 | W O 22/Rm. 5376 |
| Jennifer Mercier             | 301-796-2130 | W O 22/Rm. 5358 |

**Division of Gastroenterology Products (DGP)**

|                              |              |                 |
|------------------------------|--------------|-----------------|
| Director                     |              |                 |
| Donna Griebel, M.D.          | 301-796-2120 | W O 22/Rm. 5112 |
| Deputy Director              |              |                 |
| Joyce Korvick, M.D., M.P.H.  | 301-796-2120 | W O 22/Rm. 5114 |
| Supervisory Project Managers |              |                 |
| Julieann DuBeau              | 301-796-2120 | W O 22/Rm. 5110 |
| Brian Strongin               | 301-796-2120 | W O 22/Rm. 5116 |

**Division of Dermatology and Dental Products (DDDP)**

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| Director<br>Susan Walker, M.D. | 301-796-2110 | W O 22/Rm. 5168 |
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| Deputy Director<br>Stanka Kukich, M.D. | 301-796-2110 | W O 22/Rm. 5170 |
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| Supervisory Project Manager<br>Vacant | 301-796-2110 | W O 22/Rm. 5166 |
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#### **OFFICE OF ANTIMICROBIAL PRODUCTS (OAP)**

|                                      |              |                 |
|--------------------------------------|--------------|-----------------|
| Director<br>Edward Cox, M.D., M.P.H. | 301-796-1300 | W O 22/Rm. 6412 |
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| Deputy Director<br>Vacant |  |  |
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| Associate Director for Regulatory Affairs<br>David Roeder | 301-796-0799 | W O 22/Rm. 6410 |
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| Management Officer<br>Dana Schuhly | 301-796-0806 | W O 22/Rm. 6402 |
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#### **Division of Anti-Infective and Ophthalmology Products (DAIOP)**

|  |              |                 |
|--|--------------|-----------------|
| Director<br>Wiley A. Chambers, M.D., (Actg.) | 301-796-0690 | W O 22/Rm. 6336 |
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| Deputy Director<br>Wiley A. Chambers, M.D. | 301-796-0690 | W O 22/Rm. 6336 |
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| Deputy Director<br>Katherine Laessig, M.D. | 301-796-0746 | W O 22/Rm. 6380 |
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| Supervisory Project Managers<br>Frances LeSane | 301-796-0747 | W O 22/Rm. 6112 |
| Maureen Dillon-Parker                          | 301-796-0706 | W O 22/Rm. 6156 |

#### **Division of Anti-Viral Products (DAVP)**

|                                   |              |                 |
|-----------------------------------|--------------|-----------------|
| Director<br>Debra Birnkrant, M.D. | 301-796-0682 | W O 22/Rm. 6332 |
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| Deputy Director<br>Jeffrey Murray, M.D., MPH | 301-796-0770 | W O 22/Rm. 6360 |
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| Supervisory Project Managers<br>Vacant | 301-796-0704 | W O 22/Rm. 6330 |
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| Karen Winestock | 301-796-0834 | W O 22/Rm. 6322 |
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**Division of Special Pathogen and Transplant Products (DSPTP)**

|                                   |              |                 |
|-----------------------------------|--------------|-----------------|
| Director<br>Renata Albrecht, M.D. | 301-796-0664 | W O 22/Rm. 6168 |
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| Deputy Director<br>Steven Gitterman, M.D., Ph.D. | 301-796-0719 | W O 22/Rm. 6134 |
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| Supervisory Project Manager<br>Diana Willard | 301-796-0833 | W O 22/Rm. 6114 |
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| Supervisory Project Manager<br>Judith Milstein | 301-796-0763 | W O 22/Rm. 6170 |
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**OFFICE OF NONPRESCRIPTION PRODUCTS (ONP)**

|                                  |              |                 |
|----------------------------------|--------------|-----------------|
| Director<br>Charles Ganley, M.D. | 301-796-0895 | W O 22/Rm. 5474 |
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| Secretary<br>Norma Jiggetts | 301-796-0924 | W O 22/Rm. 5429 |
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| Deputy Director<br>Vacant |  |  |
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| Secretary<br>Vacant |  |  |
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| Associate Director<br>Susan Johnson, Pharm.D., Ph.D. | 301-796-0925 | W O 22/Rm. 5470 |
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| Management Officer<br>Merla Rae Matheny | 301-796-0955 | W O 22/Rm. 5468 |
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**Division of Nonprescription Clinical Evaluation (DNCE)**

|  |              |                 |
|--|--------------|-----------------|
| Director<br>Andrea Leonard-Segal, M.D. | 301-796-0940 | W O 22/Rm. 5416 |
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| Deputy Director<br>Joel Schiftenbauer, M.D. | 301-796-1288 | W O 22/Rm. 5478 |
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|---|--------------|-----------------|
| Program Specialist<br>Merla Rae Matheny (Actg.) | 301-796-0955 | W O 22/Rm. 5473 |
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## **Division of Nonprescription Regulation Development (DNRD)**

|  |              |                 |
|--|--------------|-----------------|
| Director<br>M. Scott Furness, Ph.D.              | 301-796-0893 | W O 22/Rm. 6474 |
| Program Specialist<br>Merla Rae Matheny, (Actg.) | 301-796-0955 | W O 22/Rm. 5468 |

## **OFFICE OF ONCOLOGY DRUG PRODUCTS (OODP)**

|   |              |                 |
|---|--------------|-----------------|
| Director<br>Richard Pazdur, M.D.                                | 301-796-2340 | W O 22/Rm. 2212 |
| Secretary<br>Vacant   |              |                 |
| Deputy Director<br>Karen Weiss , M.D.                           | 301-796-2340 | W O 22/Rm. 2208 |
| Associate Director for Regulatory Affairs<br>Glen Jones, Ph. D. | 301-796-2340 | W O 22/Rm. 2200 |
| Associate Director for Regulatory Science<br>Vacant             | 301-796-2340 | W O 22/Rm. 2202 |
| Management Officer<br>Julie Basore                              | 301-796-2340 | W O 22/Rm. 2215 |

## **Division of Biologic Oncology Products (DBOP)**

|  |              |                 |
|--|--------------|-----------------|
| Director<br>Patricia Keegan, M.D.          | 301-796-2320 | W O 22/Rm. 2320 |
| Secretary<br>Vacant                        | 301-796-1367 | W O 22/Rm. 2325 |
| Deputy Director<br>Joseph Gootenberg, M.D. | 301-796-2320 | W O 22/Rm. 2312 |
| Supervisory CSO<br>Karen Jones             | 301-796-2320 | W O 22/Rm. 2306 |

## **Division of Drug Oncology Products (DDOP)**

|                                  |              |                 |
|----------------------------------|--------------|-----------------|
| Director<br>Robert Justice, M.D. | 301-796-2330 | W O 22/Rm. 2112 |
| Secretary<br>Bertha Mejia        | 301-796-2131 | W O 22/Rm. 2125 |

|                                       |              |                 |
|---------------------------------------|--------------|-----------------|
| Deputy Director<br>Ann Farrell, M.D.  | 301-796-2330 | W O 22/Rm. 2114 |
| Deputy Director<br>Ramzi Dagher, M.D. | 301-796-2330 | W O 22/Rm. 2108 |
| Supervisory CSO<br>Frank Cross        | 301-796-2330 | W O 22/Rm. 2110 |
| Supervisory CSO<br>Dorothy Pease      | 301-796-2330 | W O 22/Rm. 2104 |

**Division of Medical Imaging and Hematology Products (DMIHP)**

|   |              |                 |
|---|--------------|-----------------|
| Director<br>Rafel (Dwayne) Rieves, M.D.           | 301-796-2050 | W O 22/Rm. 2348 |
| Secretary<br>Kimberly Miller                      | 301-796-1046 | W O 22/Rm. 2375 |
| Deputy Director<br>Liberio Marzella, M.D. (Actg.) | 301-796-2050 | W O 22/Rm. 2346 |
| Supervisory CSO<br>Kyong Kang                     | 301-796-2050 | W O 22/Rm. 2352 |

**OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY (OSE)**  
(Formerly ODS)

|   |              |                 |
|---|--------------|-----------------|
| Director<br>Gerald Dal Pan, M.D., M.H.S.                    | 301-796-2380 | W O 22/Rm. 4304 |
| Program Support Specialist<br>Barbara M McCary              | 301-796-2000 | W O 22/Rm. 4303 |
| Deputy Director<br>Henry Francis, M.D.                      | 301-796-2380 | W O 22/Rm. 4300 |
| Associate Director for Regulatory Affairs<br>Kathleen Frost | 301-796-2380 | W O 22/Rm. 4312 |

**Business Process Improvement Staff (BPS)**

|   |              |                 |
|---|--------------|-----------------|
| Staff Director<br>Henry Francis, M.D. (Actg.) | 301-796-2380 | W O 22/Rm. 4462 |
| Senior Management Officer<br>Mary Edmond      | 301-796-1786 | W O 22/Rm. 4307 |

|  |              |                 |
|--|--------------|-----------------|
| Management Officer<br>Bibi Jakrali (Actg.) | 301-796-1786 | W O 22/Rm. 3411 |
|--|--------------|-----------------|

### **Regulatory Policy Staff (RPS)**

|  |              |                 |
|--|--------------|-----------------|
| Staff Director<br>Melissa Moncavage M.P.H. (Actg.) | 301-796-2380 | W O 22/Rm. 4308 |
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### **Review Management Staff (RMS)**

|                                       |              |                 |
|---------------------------------------|--------------|-----------------|
| Staff Director<br>Sammie Beam (Actg.) | 301-796-2380 | W O 22/Rm. 4480 |
|---------------------------------------|--------------|-----------------|

### **Project Managers**

|                   |              |                 |
|-------------------|--------------|-----------------|
| Sammie Beam       | 301-796-0080 | W O 22/Rm. 3422 |
| Nancy Clark       | 301-796-1187 | W O 22/Rm. 4467 |
| Cherye Milburn    | 301-796-2084 | W O 22/Rm. 4323 |
| Janet Anderson    | 301-796-0675 | W O 22/Rm. 3435 |
| Daniel Brounstein | 301-796-0674 | W O 22/Rm. 4469 |
| Cheryl Campbell   | 301-796-0723 | W O 22/Rm. 3417 |
| Cheryl Wiseman    | 301-796-0567 | W O 22/Rm. 4467 |
| Darrell Jenkins   | 301-796-0558 | W O 22/Rm. 4483 |

### **Division of Adverse Events Analysis I (DAEA I)**

|                               |              |                 |
|-------------------------------|--------------|-----------------|
| Director<br>Mark Avigan, M.D. | 301-796-2350 | W O 22/Rm. 3478 |
|-------------------------------|--------------|-----------------|

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| Deputy Director<br>Ann McMahon, M.D. | 301-796-2350 | W O 22/Rm. 3474 |
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### **Division of Adverse Events Analysis II (DAEA II)**

|                                       |              |                 |
|---------------------------------------|--------------|-----------------|
| Director<br>Ann McMahon, M.D. (Actg.) | 301-796-2350 | W O 22/Rm. 3474 |
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| Deputy Director<br>Vacant |  |  |
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### **Division of Epidemiology (DEPI)**

|   |              |                 |
|---|--------------|-----------------|
| Director<br>Solomon Iyasu, M.D., M.P.H. | 301-796-2370 | W O 22/Rm. 4478 |
|---|--------------|-----------------|

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| Deputy Director<br>Vacant |  |  |
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### **Division of Risk Management (DRISK)**

|          |  |  |
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| Director |  |  |
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Claudia Karwoski, Pharm. D. (Actg.) 301-796-2380 W O 22/Rm. 4328

Deputy Director  
Vacant

**Division of Medication Errors and Technical Support (DMETS)**

Director  
Carol Holquist, R.Ph. 301-796-2360 W O 22/Rm. 4416

Deputy Director  
Denise Toyer, Pharm.D., R.PH 301-796-0549 W O 22/Rm. 4414

**OFFICE OF TRANSLATIONAL SCIENCES (OTS)**

Director  
ShaAvhree Buckman, M.D., Ph.D.,  
F.A.A.P. (Actg.) 301-796-1721 W O 22/Rm. 5304

Program Support Specialist  
Lisa Gilmer 301-796-1768 W O 22/Rm. 5303

Deputy Director  
ShaAvhree Buckman, M.D., Ph.D., F.A.A.P. 301-796-1653 W O 22/Rm. 5300

Senior Management Officer  
Raya S. McCree 301-796-1708 W O 22/Rm. 5314

Associate Director for Regulatory Affairs  
CDR James Lindsay Cobbs 301-796-2299 W O 22/Rm. 5462

Research Coordinator  
CAPT Frances T. Gipson 301-796-0166 W O 22/Rm. 5307

Associate Director for Science  
Jan Johannessen 301-796-2600 W O 22/Rm. 5364

**OFFICE OF BIostatISTICS (OB)**

Director  
Robert O'Neill, Ph.D. 301-796-1700 W O 22/Rm. 6212

Management Assistant  
Rosa Rivera 301-796-1018 W O 22/Rm. 6221

Deputy Director  
Edward Nevius, Ph.D. 301-796-1263 W O 22/Rm. 3238

Associate Director  
Sue Jane Wang, Ph.D. 301-796-0831 W O 22/Rm. 6216

Associate Director for Statistical Science & Policy  
Ram Tiwari 301-796-4084 W O 21/Rm. 3524

Management Officer  
Zulema Miguele 301-796-0761 W O 22/Rm. 6202

**Division of Biometrics I (DBI)**

Director  
James Hung, Ph.D. 301-796-1092 W O 22/Rm. 4238

Deputy Director  
Kooros Mahjoob, Ph.D. 301-796-1115 W O 22/Rm. 4236

**Division of Biometrics II (DBII)**

Director  
Thomas Permutt, Ph.D. 301-796-1271 W O 22/Rm. 3240

Deputy Director  
Jon Sahlroot

**Division of Biometrics III (DBIII)**

Director  
Stephen Wilson, Ph.D. 301-796-0579 W O 22/Rm. 1124

**Division of Biometrics IV (DBIV)**

Director  
Mohammad Huque, Ph.D. 301-796-1800 W O 22/Rm. 6232

Deputy Director  
Daphne Lin, Ph.D. 301-796-0751 W O 22/Rm. 6234

**Division of Biometrics V (DBV)**

Director  
Aloka G. Chakravarty, Ph.D. 301-796-1655 W O 22/Rm. 1214

**Division of Biometrics VI (DBVI)**

Director  
Stella Machado, Ph.D. 301-796-0949 W O 22/Rm. 5242

**OFFICE OF CLINICAL PHARMACOLOGY (OCP)**

(Formerly OCPB)

Director  
Lawrence J. Lesko, Ph.D. 301-796-1565 W O 51/Rm. 3178

Secretary  
Marchette Alexander 301-796-1497 W O 51/Rm. 3177

|   |              |                 |
|---|--------------|-----------------|
| Deputy Director for Science<br>Shiew-Mei Huang, Ph.D. | 301-796-1541 | W O 51/Rm. 3188 |
| Associate Director of Genomics<br>Vacant              | 301-796-1530 | W O 51/Rm. 3182 |
| Pharmacometrics Staff<br>Jogaroo Gobburu, Ph.D.       | 301-796-1589 | W O 51/Rm. 3186 |
| Management Officer<br>Malcom Dennis                   | 301-796-4107 | W O 21/Rm. 4508 |

**Division of Clinical Pharmacology I (DCPI)**

|                                |              |                 |
|--------------------------------|--------------|-----------------|
| Director<br>Mehul Mehta, Ph.D. | 301-796-1573 | W O 51/Rm. 2178 |
|--------------------------------|--------------|-----------------|

**Division of Clinical Pharmacology II (DCPII)**

|                                |              |                 |
|--------------------------------|--------------|-----------------|
| Director<br>Chandra Sahajwalla | 301-796-1599 | W O 51/Rm. 4550 |
|--------------------------------|--------------|-----------------|

**Division of Clinical Pharmacology III (DCPIII)**

|                                |              |                 |
|--------------------------------|--------------|-----------------|
| Director<br>CAPT Dennis Bashaw | 301-796-1502 | W O 51/Rm. 3134 |
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**Division of Clinical Pharmacology IV (DCPIV)**

|                                     |              |                 |
|-------------------------------------|--------------|-----------------|
| Director<br>John A. Lazor, Pharm.D. | 301-796-1559 | W O 51/Rm. 2134 |
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**Division of Clinical Pharmacology V (DCPV)**

|                                |              |                 |
|--------------------------------|--------------|-----------------|
| Director<br>Atik Rahman, Ph.D. | 301-796-1591 | W O 51/Rm. 2188 |
|--------------------------------|--------------|-----------------|

**OFFICE OF MEDICAL POLICY (OMP)**

|                                    |              |                 |
|------------------------------------|--------------|-----------------|
| Director<br>Robert J. Temple, M.D. | 301-796-2270 | W O 22/Rm. 4212 |
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| Assistant<br>Aprile Blount | 301-796-2270 | W O 22/Rm. 4217 |
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| Deputy Director<br>Rachel Behrman, M.D. (Actg.) | 301-796-2270 | W O 22/Rm. 4208 |
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| Associate Director for Regulatory Affairs<br>Janet Norden | 301-796-2270 | W O 22/Rm. 4202 |
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| Management Officer<br>Tammy Russell |  | 301-796-2270 | W O 22/Rm. 4216 |
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**Division of Drug Marketing, Advertising, and Communications (DDMAC)**

|  |  |              |                 |
|--|--|--------------|-----------------|
| Director<br>Thomas W. Abrams, RPh, MBA |  | 301-796-1200 | W O 51/Rm. 3264 |
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| Deputy Director<br>Kristin Davis |  | 301-796-1200 | W O 51/Rm. 3274 |
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**OFFICE OF INFORMATION TECHNOLOGY (OIT)**

|                           |         |              |                 |
|---------------------------|---------|--------------|-----------------|
| Director<br>James Shugars | HFD-070 | 301-827-6240 | PKLN/Rm. 10B-43 |
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| Secretary<br>Vacant | HFD-070 | 301-827-3811 | PKLN/Rm. 10B-43 |
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| Deputy Director<br>Paul McCarthy | HFD-070 | 301-827-3971 | PKLN/Rm. 10B-43 |
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| ISSO<br>Vacant | HFD-070 | 301-827-3530 | PKLN/Rm. 10B-43 |
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|---|---------|--------------|-----------------|
| Applied Technologies Staff<br>Kellie Clelland | HFD-074 | 301-827-3687 | PKLN/Rm. 10B-16 |
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| Enterprise Architecture Staff<br>Vacant |  |  |  |
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| Division of Applications Development and Services<br>Timothy Mahoney | HFD-90 | 301-827-3828 | PKLN/Rm. 10B-11 |
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|------------------------------|---------|--------------|----------------|
| Management Officer<br>Vacant | HFD-006 | 301-443-5346 | RKWII/Rm. 7214 |
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**Office of Business Process Support (OBPS)**

**Immediate Office**

|                            |  |              |                 |
|----------------------------|--|--------------|-----------------|
| Director<br>Mary Ann Slack |  | 301-796-0603 | W O 22/Rm. 1124 |
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| Deputy Director<br>Gary Gensinger |  | 301-796-0589 | W O 22/Rm. 1112 |
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| Management Officer<br>Maria Andrews |  | 301-796-2273 | W O 22/Rm. 1122 |
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|---|--------------|-----------------|
| Management Specialist<br>Kathleen Tchoulakian | 301-796-0570 | W O 22/Rm. 1131 |
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|---|--------------|-----------------|
| Program Support Specialist<br>Denise Townsend | 301-796-2112 | W O 22/Rm. 1135 |
|---|--------------|-----------------|

### **Project Development Staff (PDS)**

|                                 |              |                 |
|---------------------------------|--------------|-----------------|
| Division Director<br>Linda Sigg | 301-796-0625 | W O 22/Rm. 1114 |
|---------------------------------|--------------|-----------------|

### **Business Analysis and Reporting Staff (BARS)**

|                                    |              |                 |
|------------------------------------|--------------|-----------------|
| Division Director<br>Tasha Coleman | 301-796-1026 | W O 22/Rm. 1110 |
|------------------------------------|--------------|-----------------|

|                                       |              |                 |
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| Reports Management Team<br>Michael Cu | 301-796-0582 | W O 22/Rm. 1165 |
|---------------------------------------|--------------|-----------------|

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|---|--------------|-----------------|
| Retrieval and Analysis Team<br>Nancy Maizel | 301-796-0607 | W O 22/Rm. 1106 |
|---|--------------|-----------------|

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| <b>Regulatory Review Support Staff (RRSS)</b><br>Gary Gensinger (Actg.) | 301-796-0589 | W O 22/Rm. 1112 |
|---|--------------|-----------------|

### **Division of Records Management (DRM)**

|                                     |              |                 |
|-------------------------------------|--------------|-----------------|
| Division Director<br>Wendy Aaronson | 301-796-0410 | W O 22/Rm. 1128 |
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| Information Services Team<br>Vacant |  |  |
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| Records Repository Team<br>Vacant |  |  |
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| Records Quality Assurance Team<br>Gail Stone | 301-796-0629 | W O 22/Rm. 1112 |
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## **OFFICE OF TRAINING AND COMMUNICATIONS (OTCOM)**

|                           |              |                 |
|---------------------------|--------------|-----------------|
| Director<br>Julie Zawisza | 301-796-3700 | W O 51/Rm. 2342 |
|---------------------------|--------------|-----------------|

|   |              |                 |
|---|--------------|-----------------|
| Program Support Specialist<br>Victor Vail | 301-796-3169 | W O 51/Rm. 2341 |
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| Deputy Director<br>John Friel | 301-796-3173 | W O 51/Rm. 2350 |
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|-----------------------------------|--------------|-----------------|
| Management Officer<br>Bobbi Jones | 301-796-3175 | W O 51/Rm. 2354 |
|-----------------------------------|--------------|-----------------|

**Division of Training and Development (DTD)**

|                            |              |                 |
|----------------------------|--------------|-----------------|
| Director<br>Janice Newcomb | 301-796-3178 | W O 51/Rm. 2358 |
|----------------------------|--------------|-----------------|

|                                    |              |                 |
|------------------------------------|--------------|-----------------|
| Deputy Director<br>Virginia Giroux | 301-796-3179 | W O 51/Rm. 2362 |
|------------------------------------|--------------|-----------------|

**Division of Public Affairs (DPA)**

|                         |              |                 |
|-------------------------|--------------|-----------------|
| Director<br>Ellen Frank | 301-796-3121 | W O 51/Rm. 2236 |
|-------------------------|--------------|-----------------|

|                                   |              |                 |
|-----------------------------------|--------------|-----------------|
| Project Specialist<br>Paul G Neff | 301-796-3123 | W O 51/Rm. 2238 |
|-----------------------------------|--------------|-----------------|

|                                    |              |                 |
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| Deputy Director<br>Anthony E. Sims | 301-796-3126 | W O 51/Rm. 2244 |
|------------------------------------|--------------|-----------------|

**Division of Drug Information (DDI)**

|                         |              |                 |
|-------------------------|--------------|-----------------|
| Director<br>Barry Poole | 301-796-3145 | W O 51/Rm. 2272 |
|-------------------------|--------------|-----------------|

|                                  |              |                 |
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| Deputy Director<br>Mary Kremzner | 301-796-3144 | W O 51/Rm. 2270 |
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**Division of Information Services (DIS)**

|                    |              |                 |
|--------------------|--------------|-----------------|
| Director<br>Vacant | 301-796-3137 | W O 51/Rm. 2262 |
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|   |              |                 |
|---|--------------|-----------------|
| Deputy Director<br>Sally Winthrop (Actg.) | 301-796-3135 | W O 51/Rm. 2259 |
|---|--------------|-----------------|

**OFFICE OF COMPLIANCE (OC)**

|                                    |              |                 |
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| Director<br>Deborah M. Autor, Esq. | 301-796-3100 | W O 51/Rm. 5270 |
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| Program Support Specialist<br>Linda Hukle | 301-796-3100 | W O 51/Rm. 5271 |
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| Project Specialist<br>Marlene Sue Ling | 301-796-3361 | W O 51/Rm. 5269 |
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| Deputy Director |  |  |
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| Joseph Famulare  | 301-796-3100 | W O 51/Rm. 5266 |
| Assistant Director<br>Steve Silverman, Esq.  | 301-796-3100 | W O 51/Rm. 5276 |
| Associate Director of Scientific and<br>Medical Affairs<br>Jason Woo, M.D.                       | 301-796-3100 | W O 51/Rm. 5278 |
| Associate Director for Risk Analysis and<br>Strategic Planning<br>H. Gregg Claycamp, M.S., Ph.D. | 301-796-3130 | W O 51/Rm. 4266 |
| Associate Director of Operations<br>Terri Rumble   | 301-796-3363 | W O 51/Rm. 5272 |
| Special Assistants<br>Crystal King, P.D.,M.G.A.  | 301-796-3524 | W O 51/Rm. 5282 |
| Patricia Maroney-Benassi, Ph.D.  | 301-796-3357 | W O 51/Rm. 5262 |
| Lillian Patrician (Actg.)  | 301-796-0784 | WO 51/Rm. 6206  |
| Management Officer<br>Pam Grant  | 301-796-3368 | W O 51/Rm. 5286 |
| Regulatory Counsels<br>Heather McDowell, Esq.  | 301-796-3296 | W O 51/Rm. 5258 |
| Karena Cooper, Esq.  | 301-796-1612 | W O 51/Rm. 5252 |

**Division of New Drugs and Labeling Compliance (DNDLC)**

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| Director<br>Michael Levy, Esq.                                 | 301-796-3314 | W O 51/Rm. 5188 |
| Deputy Director<br>Kathleen Anderson, Pharm.D.                 | 301-796-3309 | W O 51/Rm. 5182 |
| Associate Director<br>Jennifer Devine (Actg.)                  | 301-796-3347 | W O 51/Rm. 5240 |
| Mandee Rosenberg, Esq.   | 301-796-3313 | W O 51/Rm. 5186 |
| Regulatory Counsel (co-located)<br>Janice Steinschneider, Esq. | 301-796-3318 | W O 51/Rm. 5196 |
| Project Management Officers (co-located)<br>Steve Lynn         | 301-796-3315 | W O 51/Rm. 5192 |
| Carrie Mampilly  | 301-796-3311 | W O 51/Rm. 5184 |
| Maryann Munson   | 301-796-3308 | W O 51/Rm. 5180 |
| OTC Drugs Team<br>Robert Heller                                | 301-796-3353 | W O 51/Rm. 5246 |

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| Internet and Health Fraud Team<br>Vacant             | 301-796-3407 | W O 51/Rm. 5368 |
| Pharmacy Compounding Team<br>Samia Nasr, R.Ph., M.S. | 301-796-3409 | W O 51/Rm. 5370 |
| New Drugs and Labeling Team<br>Jennifer Devine, Esq. | 301-796-3347 | W O 51/Rm. 5240 |
| Imports and Exports Team<br>Vacant                   | 301-796-8910 | W O 51/Rm. 5372 |

**Division of Manufacturing and Product Quality (DMPQ)**

|   |                              |                                    |
|---|------------------------------|------------------------------------|
| Director<br>Rick Friedman, M.S.   | 301-796-3268                 | W O 51/Rm. 4342                    |
| Deputy Director<br>Nick Buhay   | 301-796-3272                 | W O 51/Rm. 4348                    |
| Regulatory Counsel (co-located)<br>F. Gail Bormel, Esq.                           | 301-796-3263                 | W O 51/Rm. 4333                    |
| Project Management Officers (co-located)<br>Kennerly Chapman<br>Giuseppe Randazzo | 301-796-3271<br>301-796-3277 | W O 51/Rm. 4346<br>W O 51/Rm. 4360 |
| Recalls, Shortages & Certificates Branch<br>Mike Smedley                          | 301-796-3273                 | W O 51/Rm. 4352                    |
| Manufacturing Assessment and<br>Preapproval Compliance Branch<br>Vacant           | 301-796-3274                 | W O 51/Rm. 4354                    |
| New and Generic Drug Manufacturing Team<br>Concepcion Cruz                        | 301-796-3254                 | W O 51/Rm. 4316                    |
| International Compliance Team<br>Vacant   | 301-796-3200                 | W O 51/Rm. 4242                    |
| Biotech Manufacturing Team<br>Vacant  | 301-796-3120                 | W O 51/Rm. 4320                    |
| Case Management and Guidance Branch<br>Vacant                                     | 301-796-3120                 | W O 51/Rm. 4358                    |
| Case Management Team<br>Teddi Lopez   | 301-796-3255                 | W O 51/Rm. 4318                    |
| Guidance and Policy Development Team  |                              |                                    |



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| Brian Hasselbalch | 301-796-3279 | W O 51/Rm. 4364 |
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### **Division of Compliance Risk Management and Surveillance (DCRMS)**

|  |              |                 |
|--|--------------|-----------------|
| Director<br>H. Gregg Claycamp, M.S., Ph.D.                                     | 301-796-3130 | W O 51/Rm. 4266 |
| Deputy Director<br>Anthony Orenca, MD.   | 301-796-0963 | W O 51/Rm. 4274 |
| Project Management Officer (co-located)<br>Karen Kirchberg                     | 301-796-3233 | W O 51/Rm. 4270 |
| Surveillance and Data Analysis Branch<br>Vacant                                | 301-796-3235 | W O 51/Rm. 4272 |
| Risk Management and Strategic<br>Problem Solving Team<br>Suzanne Barone, Ph.D. | 301-796-3224 | W O 51/Rm. 4258 |
| Surveillance Programs Team<br>Ralph (Jay) Schmid                               | 301-796-3231 | W O 51/Rm. 4268 |
| Data Analysis and Information<br>Management Team<br>Brenda Wang                | 301-796-3532 | W O 51/Rm. 4282 |
| Drug Registration & Listing Team<br>John Coburn                                | 301-796-3237 | W O 51/Rm. 4278 |
| Drug Quality Reporting System<br>Direct Line                                   | 301-796-3140 |                 |

### **Division of Scientific Investigations (DSI)**

|  |              |                 |
|--|--------------|-----------------|
| Director<br>Leslie Ball, M.D.                            | 301-796-3150 | W O 51/Rm. 5342 |
| Deputy Director<br>Joseph Salewski                       | 301-796-3395 | W O 51/Rm. 5348 |
| Good Clinical Practice Branch I<br>Constance Lewin, M.D. | 301-796-3397 | W O 51/Rm. 5354 |
| Good Clinical Practice Branch II<br>Vacant               | 301-796-3150 | W O 51/Rm. 5356 |
| GLP/Bioequivalence Investigations Branch                 |              |                 |

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| C.T. Viswanathan, Ph.D. | 301-796-3394 | W O 51/Rm. 5346 |
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| Project Management Officer (co-located)<br>Leslie Vaccari | 301-796-3396 | W O 51/Rm. 5350 |
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**OFFICE OF COUNTER-TERRORISM AND EMERGENCY COODINATION (OCTEC)**

|                                    |              |                 |
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| Director<br>Rosemary Roberts, M.D. | 301-796-2210 | W O 21/Rm. 1626 |
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| Deputy Director<br>Brad Leissa, M.D. | 301-796-2210 | W O 21/Rm. 1624 |
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| Program Support Specialist<br>Darlene Johnson | 301-796-1685 | W O 21/Rm. 1645 |
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| Assoc. Dir. Emergency Risk Communication<br>Susan McCune, M.D. | 301-796-1709 | W O 21/Rm. 1611 |
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| Associate Director for Regulatory Affairs<br>Joanne Holmes, R.Ph. | 301-796-1681 | W O 21/Rm. 1622 |
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| Management Officer<br>Karen D. Smith | 301-796-1756 | W O 21/Rm. 1673 |
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