CDRH OMBUDSMAN ANNUAL REPORT

Calendar Year 2001

The CDRH Ombudsman, Les Weinstein, was appointed to this new position, located in the Office of the Center Director, in April, 2000. As an external Ombudsman, he investigates complaints from outside the agency, and facilitates the resolution of disputes between CDRH and the medical device industry it regulates. While providing this assistance, he maintains his impartiality and neutrality. A complaint is usually an expression of dissatisfaction, perhaps about timeliness, lack of communication, or an unhelpful employee. A dispute usually involves a disagreement with, a challenge to, or an appeal of a decision or action the Center has taken or is about to take. The Ombudsman also receives a wide variety of device related questions from the public of a scientific, regulatory, or procedural nature. This Report includes statistics on complaints, disputes, and questions as well as information on some other activities and initiatives the Ombudsman has undertaken. You may also wish to see his web site at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

This Annual Report is the first one the Ombudsman is issuing for a full calendar year. His 2000 Annual Report covered only the initial nine months that he was in this position, but statistics from that Report are included below for limited comparison purposes.

I. COMPLAINTS AND DISPUTES

Number Received:

	2001	**2000 (April – December)**
Complaints	51	24
Disputes	21	11
Total	72	35

When Ombudsman was contacted: (If related to a process such as submissions.)

	2001	**2000**
As last resort	17%	N/A
Earlier	60%	N/A

Office: (Some involved more than one Office.)

	2001	2000
ODE	65%	61%
OC	27%	18%
OSB	3%	N/A
OHIP	3%	N/A
OSM	3%	N/A

ODE by Division:

	2001	2000
DRARD	4%	4%
DCLD	16%	9%
DGRND	31%	39%
DDIGD	12%	22%
DCRD	22%	26%
DOED	2%	0%
POS	12%	N/A

Subjects:

	2001	2000
510(k)	41%	51%
PMA	9%	6%
Inspections	8%	N/A
IDE	4%	N/A
Imports	4%	N/A
Drugs of Abuse Tests	4%	N/A
Advertising/Promotion	3%	N/A
CLIA	3%	N/A
AIP	3%	N/A
Reuse	1%	N/A
Leveraging	1%	N/A
Recalls	1%	N/A
Petitions	1%	N/A
Registration/Listing	1%	6%
Website	1%	N/A
FOI	1%	N/A
Other	14%	37%

Issues by rank: (Some Complaints/Disputes involved more than issue.)

	2001	2000
1. Evidence requirements (data, testing) to support a submission; "least burdensome"	20%	15% (2)*
2. Policy/Procedures	18%	7% (4)
3. Timeliness (of approval/clearance; setting up meetings; returning phone calls; etc.)	17%	13% (3)
4. Miscommunication or lack of communication	15%	23% (1)
5. Level playing field (concerns regarding unequal treatment)	11%	4% (8)
6. Rude, difficult or unhelpful employees	2%	7% (5)
7. Claims of conflict of interest, bias, retaliation	2%	7% (6)
8. Jurisdiction over combination (drug/device) products	1%	3% (9)
9. Disclosure (FOIA)	1%	5% (7)
10. Allegations of employee incompetence	0%	3% (10)
11. Other	13%	15%

*Numbers in parentheses indicate ranking last year.

Status:

	2001*	2000
Pending at year's end	36%	37%
Referred elsewhere	12%	11%
Withdrawn	13%	N/A
Resolved	39%	51%

*Includes 72 complaints/disputes received in 2001 and 13 pending at the end of 2000 and carried over to 2001.

Outcomes: (Of the complaints/disputes that were resolved.)

	2001	2000
In favor of industry	39%	42%
In favor of CDRH	21%	17%
Mutual satisfaction	39%	41%

Status and outcomes of complaints/disputes that involved evidence requirements as an issue:

	2001	2000
Resolved	54%	N/A
In favor of industry	27%	N/A
In favor of CDRH	47%	N/A
Mutual satisfaction	27%	N/A

II. QUESTIONS

In addition to his involvement in complaints and disputes, the Ombudsman receives many device related questions from the public by phone, fax and email to which he responds, often in consultation with other CDRH offices, or refers to those offices for a direct reply.

	2001	2000
Number Received	101	29

From:

	2001	2000
Industry	56%	41%
Consumers	25%	28%
Health care providers	15%	10%
State government	3%	N/A
Media	2%	N/A
Academia	1%	N/A
Other	0%	21%

Subjects: (Five most common.)

	2001	2000
Status of submission	10%	14%
IDE/human subjects	9%	14%
Combination products	9%	10%
Imports	7%	N/A
Labeling	5%	10%

III. DISPUTE RESOLUTION PANEL

On July 2 the Guidance for industry and FDA, entitled "Resolving Scientific Disputes Concerning the Regulation of Medical Devices: a Guide to Use of the Medical Devices Dispute Resolution Panel," was issued in Final. This Guidance is available at http://www.fda.gov/cdrh/resolvingdisputes/1121.pdf.

The Ombudsman granted the first request for the newly created Medical Devices Dispute Resolution Panel to review a scientific dispute. The request was submitted by Lifecore Biomedical which was appealing a decision by CDRH that Lifecore's pre-market approval application (PMA) for Intergel Adhesion Prevention Solution was not approvable. The Panel meeting was held on September 6. The Panel voted unanimously to recommend that the PMA be approved. The Center Director subsequently concurred with this recommendation, and the PMA was approved. No other requests for review of a dispute by this Panel have been received.

IV. QUALITY ASSURANCE SURVEYS

As part of his Quality Assurance Manager role, the Ombudsman attends meetings that Center staff has with device firms and sponsors. Afterwards he surveys the industry participants to get feedback on the meeting. The Ombudsman also surveyed sponsors and applicants on their experiences specifically with Agreement and Determination Meetings and with Day 100 Meetings.