Exhibit 6-31
EXAMPLE OF COMPLAINT FOR INJUNCTION AND CIVIL PENALTY

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	Civil Action
v.	)	No.
ABC COMPANY, INC., a corporation,	)	Judge
And	)	
ALAN R. SMITH, an individual,	)	
Defendants	)	

COMPLAINT FOR PERMANENT INJUNCTION AND FOR CIVIL PENALTIES

The United States of America, plaintiff, by its undersigned attorneys, respectfully represents to this Honorable Court as follows:

INTRODUCTION

1. This action is brought pursuant to the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 360pp to:

a. enjoin and restrain the defendants from violating 21 U.S.C. 360oo(a)(1), (a)(2), and (a)(5)(B), and

b. enforce the Act's radiological health civil penalty provisions, 21 U.S.C. 360pp(b)(1), in accordance with 28 U.S.C. 1355.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. 360pp(a) and 28 U.S.C. 1331, 1337, 1345, and 1355.

3. Venue in this district is proper pursuant to 21 U.S.C. 360pp(c), 28 U.S.C. 1391(b), and 28 U.S.C. 1395(a).

COUNT ONE

(Presenting a Cause of Action to Restrain Violations of 21 U.S.C. 360oo)

4. Defendant ABC Company, Inc. (ABC), is a corporation organized and existing under the laws of the State of Illinois and at all times relevant to the allegations in this Complaint, trading and doing business at 38 Main Street, Peoria, Illinois, within the jurisdiction of this Court. The firm became incorporated on March 23, 1967.

5. Defendant, Alan R. Smith, an individual, is and has been since 1989, the President and Chief Executive Officer of ABC. Prior to that time, Mr. Smith was the firm's Vice President. He also currently holds the position of Corporate Treasurer. At all times relevant to this action, Mr. Smith performed his duties at 38 Main Street, Peoria, Illinois, within the jurisdiction of this Court. Mr. Smith has ultimate responsibility for all facets of the firm's operations.

6. Defendants are, and at all times relevant to this action have been, engaged in the business

of importing and manufacturing diagnostic x-ray systems which are "electronic products" within the meaning of 21 U.S.C. 360hh(2). Accordingly, each defendant was and is a "manufacturer" of electronic products within the meaning of 21 U.S.C. 360hh(3).

Failure to Cease Introduction of Violative Products Into Commerce

7. Pursuant to 21 U.S.C. 360ii(a), the Commissioner of Food and Drugs under authority delegated to him by the Secretary of Health and Human Services ("Secretary") under 21 CFR 5.10(a)(3), promulgated regulations prescribing performance standards for diagnostic x-ray systems and their major components. These regulations are codified, in pertinent part, at 21 CFR 1020.30-33.

8. On August 9, 1993, the United States Food and Drug Administration ("FDA") notified defendants that their model 12 x-ray systems failed to meet, inter alia, the light localizer illuminance requirements, the contrast ratio requirements, and the labeling and certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 1010.2, respectively.

9. X-ray systems use a light localizer to define the light field so the operator of the equipment can adjust the x-ray field to the proper image receptor site. The contrast ratio requirement exists to permit the operator to align the film with the edges of the x-ray field. Failure of a system to meet these two requirements could cause the operator to visualize inaccurately the x-ray field, and could result in an x-ray field that is larger than necessary for the examination. An x-ray field that is too large or misaligned could overexpose the patient to radiation, and could unnecessarily expose sensitive body organs to radiation. If critical organs are exposed to radiation, there is an increased risk to the patient of cell damage and cancer.

10. Defendants met with FDA’s CDRH on September 24, 1993. At that time, CDRH notified defendants that their mobile and wall-mounted podiatry x-ray systems, models 13, 14, 15, and 16, and their portable, general purpose x-ray systems, models 17 and 18, all failed to meet the requirements cited in the Warning Letter of August 9, 1993. By follow-up letter dated October 5, 1993, and by second Warning Letter dated January 6, 1994, CDRH reiterated to defendants that all of the above-mentioned units were noncompliant. On February 16, 1994, CDRH approved a corrective action plan for the podiatry units defendants placed into commerce prior to August 9, 1993. CDRH notified defendants that they were to submit a corrective action plan for the general purpose x-ray systems. From August 9, 1993 through March 30, 1995, the defendants exchanged numerous correspondences with CDRH and FDA’s Chicago District regarding the noncompliance of the x-ray units.

11. Nevertheless, after September 24, 1993, the date on which FDA notified defendants that their mobile and wall-mounted podiatry x-ray systems and their portable, general purpose x-ray systems did not comply with the applicable performance standards, the defendants sold the following 22 units in violation of applicable performance standards, including 16 model 13 units, 1 model 15 unit, 1 model 17 unit, and 4 model 18 units:

Model 13 Units (16 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
03/16/94	20603	16226	Podiatry Supply Co. (Heights, OH)
05/05/94	21004	16218	"
12/01/94	22625	16996	"
		16997	"
05/25/94	21175	16645	"
		16646	"
		16649	"
06/06/94	21235	16235	"
		16648	"
		16651	"
03/28/94	20668	16232	Healthcare (Brooklyn, NY)
10/04/94	22221	15549	Podiatry (Stony Brook, NY)
11/11/93	19660	13682	Supply Service (Gettysburg, PA)
04/20/94	20885	16231	"
12/13/94	22708	16223	"
02/07/95	23194	17002	"

Model 15 Unit (1 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
03/23/94	20635	16650	Podiatry (Stony Brook, NY)

Model 17 Unit (1 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
09/28/93	19359	16116	Supply Service (Gettysburg, PA)

Model 18 Units (4 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
10/15/93	19486	16360	Tech, Inc. (Walnut, CA)
01/06/94	20033	16357	Ocean, Ltd. (San Jose, CA)
		16363	"
03/09/94	20495	16361	A.S. (Calcutta, India)

By introducing into commerce these 22 x-ray systems that did not comply with the applicable performance standards, defendants committed 22 violations of 21 U.S.C. 360oo(a)(1).

12. Between March 20, 1991 and September 24, 1993, the date on which defendants were notified that their mobile and wall-mounted podiatry x-ray systems and their portable general purpose x-ray systems violated the applicable performance standards, defendants introduced into commerce the following 121 x-ray systems in violation of applicable performance standards, including 27 model 15 units, 1 model 16 unit, 49 model 13 units, 10 model 14 units, 15 model 17 units, and 19 model 18 units:

Model 15 Units (27 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
08/01/91	13639	14418	Medical Equipment Co. (Chicago, IL)
06/09/93	18608	16119	X-Ray Supply Corp. (Miami, FL)
12/18/91	14629	14424	Podiatry Supply Co. (Heights, OH)
		14427	"
01/29/92	14906	14576	"
04/23/92	15588	15434	"
03/11/93	17949	16040	"
09/06/91	13904	14262	Healthcare (Brooklyn, NY)
10/02/91	14066	14423	"
12/05/91	14507	14432	"
01/24/92	14858	14582	"
04/23/92	15577	15446	"
05/22/92	15824	15439	"
06/12/92	15966	15444	"
	15967	15435	"
04/02/91	12728	14258	Equipment Distributors (Syossett. NY)
12/05/91	14465	14428	"
01/03/92	14691	14585	"
01/22/92	14827	14580	Podiatry, Inc. (Freeport, NY)
02/14/92	15029	14567	"
05/21/91	13100	14259	Supply Service (Tyler Hill, PA)
01/21/93	17558	16031	"
02/11/93	17753	16034	"
		16045	"
03/16/93	17993	16030	"
		16041	"
04/21/93	18296	16123	"

Model 16 Unit (1 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
01/28/93	17633	15339	Podiatry, Inc.(Freeport, NY)

Model 13 Units (49 total)

	INVOICE#	SERIAL#	SOLD TO
03/20/91	12628	14256	Flag X-Ray (Bay, NY)
08/20/92	16439	15542	Medical Equipment Co. (Chicago, IL)
09/15/92	16629	15544	"
11/11/92	17068	15975	"
02/12/93	17768	16042	"
02/23/93	17830	16049	"
03/22/93	18030	16033	"
08/04/93	18990	16121	"
03/20/91	12630	14260	Supply Co. (Akron, OH)
		14264	"

		14269	"
12/18/91	14629	14421	"
03/10/92	15245	13669	"
04/08/92	15490	14583	"
04/23/92	15588	15437	"
		15442	"
06/01/92	15893	15427	"
09/11/92	16610	15533	"
		15538	"
		15543	"
		15551	"
09/25/92	16721	15545	"
03/11/93	17949	15977	"
09/01/93	19202	16236	"
		16237	"
03/20/91	12631	14261	Podiatry Supply (Islip, NY)
	12632	14266	"
04/23/91	12893	14255	"
12/19/91	14620	14417	"
		14577	"
02/26/92	15144	14584	Healthcare Distributors, Inc. (Palo Alto, CA)
03/10/92	15235	14425	"
05/27/92	15843	15436	"
06/30/92	16111	15430	"
09/15/92	16609	15540	"
11/11/92	17070	15973	"
		15980	"
11/11/92	17073	15978	Medical Supply (Reno, NV)
04/12/91	12829	14253	Medical Healthcare (Montauk, NY)
07/30/92	16326	15537	Stone & Palo, Inc. (Plainview, NY)
08/27/93	19180	16222	"
06/20/91	13341	14263	Best Service (Philadelphia, PA)
12/12/91	14600	14419	"
12/23/91	14653	14570	"
09/14/92	16605	15547	"
09/15/92	16630	15539	"
02/11/93	17753	16037	"
03/16/93	17993	16036	"
12/10/92	17288	15979	Eastern Supply, Inc. (Boston, MA)

Model 14 Units (10 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
11/09/92	17043	15340	Equipment & Supply (Denver, CO)
02/12/93	17768	15471	"
08/04/92	16348	15475	B & S Supply Co. (Pittsburgh, PA)
05/26/93	18584	16271	"
01/21/93	17562	15219	Chris & Sons (Las Vegas, NV)
03/25/92	15347	15224	Pebbles & Sam Co. (Phoenix, AZ)
01/04/93	17435	15215	"
11/20/92	17127	15338	Foot Service Inc. (Maspeth, NY)
01/21/93	17558	15335	"
06/09/93	18619	16282	Southern Supply (San Jose, CA)

Model 17 Units (15 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
01/07/92	14739	14430	BB X-Ray (Detroit, MI)
01/14/92	14781	14575	"
09/23/92	16689	15541	"
07/08/91	13452	14270	Advantage Podiatry (Atlanta, GA)
06/03/91	13203	14429	Veterinary Supply (Baldwin, NY)
05/05/92	15670	15432	Tech, Inc. (Walnut, CA)
03/22/93	18029	16044	Podiatry Supply Co. (Heights, OH)
04/09/93	18210	16118	"
05/17/93	18470	16047	"
12/16/92	17335	16035	Brokerage (Orlando, FL)
		16048	"
11/13/91	14354	14420	S & S X-Ray Service (Pittsburgh, PA)
06/25/93	18729	16032	"
10/04/91	14089	14251	X-Ray Supply (Provo, UT)
05/05/92	15682	15440	B.C.A. Inc. (San Francisco, CA)

Model 18 Units (19 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
04/22/93	18309	16270	36 X-Ray (Greenwood Lake, NY)
05/05/92	15670	15222	Tech, Inc. (Walnut, CA)
05/14/93	18592	16364	Tech, Inc. (Walnut, CA)
		16365	"
08/23/93	19135	16359	"
05/11/93	18424	16273	Industries Inc. (Atlantic City, NJ)
04/07/93	18195	15216	X-Ray Service (Terra Haute, IN)

09/22/92	16680	15224	Available Supply (Boise, ID)
11/06/92	17034	15341	"
		15477	"
02/02/93	17662	14878	"
		15342	"
03/17/93	17999	15224	"
04/13/93	18234	16268	"
04/14/93	18238	16272	"
06/07/93	18605	16275	"
08/09/93	19019	16274	"
		16283	"
05/07/93	18400	16276	California Labs (Los Angeles, CA)

By introducing into commerce these 121 x-ray systems that did not comply with the applicable performance standards, defendants committed 121 violations of 21 U.S.C. 360oo(a)(1).

Failure to Meet Certification Requirements

13. Pursuant to 21 U.S.C. 360kk(h), every "manufacturer" of an electronic product to which a performance standard is applicable is required to certify that such product conforms to all applicable performance standards. Such certification shall be based upon a test, in accordance with the performance standards, of the individual article to which it is attached. The manufacturer must furnish that certification to the dealer or distributor, in the form of a label or tag permanently affixed to or inscribed on such product. 21 CFR 1010.2.

14. Defendants failed to comply with the certification requirements for electronic products when they certified that the 22 podiatry units described in paragraph 11 met all applicable performance standards. The defendants, in the exercise of due care, had reason to know that such certifications were false or misleading in a material respect, in that FDA had notified them that the units failed to meet the applicable performance standards. Therefore, by affixing materially false or misleading certifications to the 22 units described in paragraph 11, the defendants committed 22 violations of 21 U.S.C. 360oo(a)(5)(B).

Failure to Notify and Failure to Repair, Replace, or Refund

15. Pursuant to 21 U.S.C. 360ll, every manufacturer of electronic products who discovers that an electronic product produced, assembled, or imported by him does not comply with the performance standards, must immediately notify the Secretary and the dealers, distributors, and/or first purchasers of any electronic products that have a defect or that do not comply with any applicable performance standard, and must also: (l) without charge, bring such product into conformity with the applicable standard or remedy such defect; (2) replace each product with a like or equivalent product which complies with each applicable standard; or (3) refund the cost of such product. The Commissioner has promulgated regulations, 21 CFR 1002, 1003, and 1004, which prescribe how such notification and correction shall be accomplished.

16. FDA determined that the 143 units described in paragraphs 11 and 12 did not comply with the light localizer, contrast ratio, and labeling and certification requirements, 21 CFR 1020.31(d)(2)(ii) and (iii) and 1010.2, respectively.

17. Moreover, defendants sold 127 units in violation of applicable performance standards from January 21, 1988 to February l9, 1991. The sales of the 127 units included 71 model 15 units, 50 model 13 units, and 6 model 17 units, and were as follows:

Model 15 Units (71 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO

01/21/88	4217	11549	Medical Co. (Brook, MN)
05/09/88	5060	11944	"
06/15/88	5335	12007	"
		12008	"
11/07/88	6421	12428	"
01/13/89	6901	12314	"
07/17/89	8314	12903	"
05/02/90	10435	13670	"
01/21/88	4218	11551	Podiatry Supply Co. (Heights, OH)
01/28/88	4261	11550	"
		11559	"
		11566	"
05/04/88	5026	11953	"
		11955	"
		11964	"
01/13/89	6902	12425	"
		12426	"
02/01/89	7043	12320	"
08/22/89	8537	12910	"
09/11/89	8671	12902	"
10/18/89	8949	12891	"
	8950	12890	"
01/30/90	9727	13020	"
		13031	"
04/07/90	10264	13026	"
04/10/90	10271	13664	"
08/14/90	11180	13776	Flower Podiatry Supply (Morristown, NJ)
12/05/89	9295	13032	Dental/Medical and Co. (Blacksburg, VA)
		13038	"
01/29/89	7026	12423	Equipment Distributors (Monticello, NY)
02/24/89	7264	12420	"
		12430	"
03/14/89	7387	12325	"
05/09/89	7874	12664	"
		12670	"
06/21/89	8161	12892	"
06/21/89	8162	12900	"
07/25/89	8362	12893	"

08/30/89	8592	12887	"
10/16/89	8952	12895	"
02/05/90	9794	13021	"
04/03/90	10220	13674	New York Distributors (Albany, NY)
05/14/90	10532	13665	"
09/11/90	11377	14056	"
		14062	"
11/29/90	11878	14217	New York Medical Co. (Geneva, NY)
12/21/90	12035	14218	"
12/11/89	9337	13040	Green Surgical Supply (Dayton, OH)
02/22/89	7263	12315	Supply Service (Groton, CT)
		12317	"
		12318	"
		12326	"
		12328	"
08/23/89	8590	12897	"
09/13/89	8690	12915	"
		13041	"
		13049	"
10/10/89	8891	12888	"
		12908	"
		12916	"
11/29/90	11879	14223	"
		14224	"
01/20/91	12210	14230	"
12/08/89	9327	13024	C & R X-Ray (Birmingham, AL)
		13036	"
		13045	"
08/15/90	11195	13773	"
		13780	"
		13782	"
		13787	"
		13790	"

Model 13 Units (5O total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
01/27/88	4243	11571	Equipment Co. (Olney, MD)
	4244	11568	"
03/21/88	4687	11059	"
		11569	"

05/05/88	5039	11954	"
		11957	"
06/15/88	5334	12018	"
		12031	"
07/06/88	5490	11948	"
10/07/88	6178	12022	"
10/26/88	6317	12020	"
12/06/88	6631	12024	"
02/03/89	7054	12319	"
05/22/90	10587	13673	"
01/18/91	12198	14252	"
03/22/88	4735	11507	Podiatry Supply Co. (Heights, OH)
05/04/88	5027	11952	"
		11958	"
02/07/89	7068	12323	"
03/27/89	7537	12019	"
04/04/89	7603	12673	"
		12675	"
05/08/89	7860	12667	"
		12669	"
11/10/89	9133	13025	"
02/13/90	9884	13468	"
03/29/90	10182	13668	"
		13677	"
04/07/90	10264	13034	"
08/28/90	11277	14063	"
06/21/89	8175	12913	Podiatry Supply (Buffalo, NY)
07/17/89	8317	12896	"
08/14/89	8493	12889	"
01/26/90	9697	13465	"
03/01/90	9987	13464	"
03/29/90	10204	13679	"
07/19/90	10984	13774	"
01/29/89	7026	12421	Medical Equipment Inc. (New Orleans, LA)
08/30/89	8591	12914	"
01/28/90	9698	13023	"
05/14/90	10531	13672	New York Supply (Tarrytown, NY)
09/11/90	11377	14058	"
12/11/90	11962	14229	Medical Equipment Inc. (Erie, PA)
09/06/89	8632	13035	Surgical Supplies (Louisville, KY)
02/02/90	9783	13473	"
03/21/89	7491	12322	Service for Surgery (Dover, DE)

		12427	"
11/29/90	11880	14225	"
01/02/91	12106	14216	"
01/20/91	12210	14221	"

Model 17 Units (6 total)

SHIPPING DATE	INVOICE#	SERIAL#	SOLD TO
02/08/91	12356	14226	S-5 X-Ray (St. Louis, MO)
02/19/91	12433	14228	Associate Radiology (Seattle, WA)
01/01/91	12157	13997	A & A X-Ray (Scranton, PA)
01/23/91	12213	14055	"
11/02/90	11741	13997	X-Ray Supply (Dallas, TX)
11/29/90	11881	14226	SMA Surgical Supply (Houston, TX)

18. On February 16, 1994, FDA notified defendants that for all of the 270 violative units that were already in commerce, they were required to notify the first purchasers, dealers, or distributors of the x-ray units, and the end-users of such products, as required by 21 U.S.C. 360ll(e), and they were further required to: (1) without charge, bring such products into conformance with the standard; (2) replace the products with like or equivalent products; or (3) make a refund of the cost of the products, as required by 21 U.S.C. 360ll(f).

19. Nevertheless, defendants failed to notify the first purchasers, dealers, or distributors and end-users of the 270 x-ray units described in paragraphs 11, 12, and 17, and they failed to (1) without charge, bring such products into conformance with the standard, (2) replace the products with like or equivalent products, or (3) refund the cost of the products, thereby committing 270 violations of 21 U.S.C. 360oo(a)(2).

COUNT TWO

(Presenting a Cause of Action to Enforce the Civil Penalties Provisions of 21 U.S.C. 360pp(b)(1))

20. This Count realleges and incorporates by reference paragraphs 1 through 19 of this Complaint as if fully set forth herein.

21. Pursuant to 21 U.S.C. 360pp(b)(1), any person who violates 21 U.S.C. 360oo shall be subject to a civil penalty of not more than $1,000. Any violation with respect to any act or omission made unlawful by 21 U.S.C. 360oo constitutes a separate violation for purposes of 21 U.S.C. 360pp(b)(1), and the maximum civil penalty imposed on any person for any related series of violations is not to exceed $300,000.

22. Each defendant committed a total of 435 violations of 21 U.S.C. 360oo, including: (1) 143 violations of 21 U.S.C. 360oo(a)(1); (2) 22 violations of 21 U.S.C. 360oo(a)(5)(B); and (3) 270 violations of 21 U.S.C. 360oo(a)(2). For each violation, a civil penalty of $1,000 may be imposed. Therefore, under 21 U.S.C. 360pp, a civil penalty of $300,000 per defendant may

be imposed.

WHEREFORE PLAINTIFF PRAYS:

I. That defendants, ABC and Alan R. Smith, and all of their officers, agents, representatives, employees, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with them, or any of them, be permanently restrained and enjoined under the provisions of 21 U.S.C. 360pp(a) from directly or indirectly doing or causing to be done any of the following acts:

a. Introducing, or delivering for introduction into commerce as defined in 21 U.S.C. 360hh(4), any diagnostic x-ray system subject to, but not in compliance with, applicable performance standards in 21 CFR 1010 and 1020;

b. Issuing certification that x-ray equipment meets the applicable standards when they, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect;

c. Failing to comply with 21 U.S.C. 360oo(a)(2), which specifically requires manufacturers to (1) notify the purchasers of x-ray equipment that it does not comply with the performance standards; and (2) without charge, bring their manufactured diagnostic x-ray systems into conformity with the applicable standards prescribed in 21 CFR 1010 and 1020, or replace such products with a like or equivalent product that complies with the applicable standards, or refund the cost of the violative products;

d. Failing to implement the FDA-approved corrective action plan for ABC's mobile and wall-mounted podiatry x-ray systems, models 13, 14, 15, and 16; and

e. Failing to submit and implement a corrective action plan for ABC's portable, general purpose x-ray systems, models 17 and 18.

II. That the defendants, ABC and Alan R. Smith, each be required to pay to the plaintiff a civil penalty, pursuant to 21 U.S.C. 360pp(b)(1), in the amount of $300,000, for the violations herein above alleged in paragraphs 7 through 19. This amount represents a penalty to each defendant of $1,000 per violation of 21 U.S.C. 360oo, up to the maximum penalty of $300,000 per defendant allowed pursuant to 21 U.S.C. 360pp(b)(1).

III. That the plaintiff be granted judgment for its costs herein, and that this court grant such other and further as it deems just and proper.

Dated this [insert date] day of [insert month and year].

Respectfully submitted,

[insert name]
Assistant Attorney General

[insert name]
United States Attorney

[insert name]
Assistant U.S. Attorney
[insert address]
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