Protection Act of 1986 (ECPA). In so doing, the majority is usurping the role of Congress. As O&R pointed out in its Petition at page 22, the Supreme Court cautioned that the "broad purposes" of legislation must not be invoked at the expense of the actual terms of the statute. In *Board of Governors of Federal Reserve System v. Dimension Financial Corporation*, 474 U.S. 361 (1986), the Court reasoned:

Application of 'broad purposes' of legislation at the expense of specific provisions ignores the complexity of the problems Congress is called upon to address and the dynamics of legislative action. Congress may be unanimous in its intent to stamp out some vague social or economic evil; however, because its Members may differ sharply on the means for effectuating that intent, the final language of the legislation may reflect hard fought compromises. Invocation of the 'plain purpose' of legislation at the expense of the terms of the statute itself takes no account of processes of compromise and, in the end, prevents the effectuation of congressional intent. *Id.* at 373. *See also* EEI Petition at page 15 and cases cited therein.

In addition to the legal flaws contained in the majority's order, there are factual ones as well. As discussed in my August 17th dissent (slip op. at 8–11) and in EEI's Petition (at 7–9), the majority misuses the Congressional testimony of Edward G. Horn, chief ecologist for New York State Department of Environmental Conservation, which was contained in the House Report on ECPA. As EEI's Petition points out, all of Mr. Horn's concerns apply equally to lawfully unlicensed projects and unlawfully unlicensed projects. In the instant order, the majority once again distorts the legislative history by using Mr. Horn's remarks for the proposition that Congress intended section 31(c) penalties to apply to unlicensed owners. Moreover, delving into the legislative history at the expense of the plain words of the statute treads dangerous ground as the D.C. Circuit Court recently opined in *Abourezk v. Reagan*, 785 F.2d 1043 (D.C. Cir. 1986):

[W]e think it plainly wrong as a general matter * * * to regard committee reports as drafted more meticulously and as reflecting the congressional will more accurately than the statutory text itself. Committee reports, we remind, do not embody the law. Congress, as Judge Scalia recently noted, votes on the statutory words, not on different expressions packaged in committee reports. *Hirschey v. FERC*, 777 F.2d 1, 7–8 & n.1 (D.C. Cir. 1985) (Scalia, J., concurring).

EEI's Petition also highlights other administrative civil penalty statutes and pointed out that these enactments including section 31(c), are similar in form and, because they address the same subject matter—administrative enforcement by civil penalty—should be read together to ascertain the meaning of any one (EEI Petition at 10–15). Examples cited are section 234(a) of the Atomic Energy Act of 1954, and section 11901 of the Interstate Commerce Act as extensively amended in 1978. EEI argues that there is no reason to suggest that Congress meant anything other than what it said in section 31(c) inasmuch as Congress has in other enactments taken care precisely to delimit the scope of civil penalty liabilities in terms of the entities against which penalties may be assessed. The instant rehearing order fails to address this important point.

I do not wish to diminish the genuine concern with which my colleagues view the unlicensed projects issue, though in my view at least this should not concern us as much as my colleagues seem to think. However, notwithstanding our disagreement on the gravity of the problem, it is important to note that the Commission for many years has had procedures in place to effectively deal with unlicensed projects without the use of civil penalties, another fact the majority completely ignores.

For example, in the so-called *Androscoggin* decision, *Public Service Co. of New Hampshire*, 27 F.P.C. 830 (1962), the Commission identified three principal factors to be taken into account when considering cases involving the unlicensed project issue: (1) to the extent feasible, it is the burden of a sound licensing policy to minimize the inequity of an unlicensed project owner reaping a windfall from a delay in filing for a required license; (2) the Commission's past failure, for want of funds or manpower, to enforce general compliance and the large number of projects that had operated without a license since 1935 indicated the need for a discriminating approach in order to effectively address the unlicensed project issue; and (3) in regard to termination date of a license, it was reasonable to shorten the license term to take account of significant 1943 decisions holding navigable a stream usable for log transport, and thus giving notice of the perils of further unlicensed operation to the owner of a project in such a stream. So the Commission fixed December 3, 1993—fifty years after that 1943 notice—as the termination date of the Androscoggin license.

Moreover, several years after *Androscoggin*, the D.C. Circuit Court enhanced the Commission's ability to deal effectively with the unlicensed project issue by citing with approval the *Androscoggin* decision and by expressly holding that the Commission has statutory authority to assign an effective date for licenses issued to a project owner earlier than the date of issuance of license when the project involved was one constructed or maintained without a license in violation of law. *See Niagara Mohawk Power Corporation v. FPC*, 379 F.2d 153 (D.C. Cir. 1967). This procedure could include in appropriate cases the assessment of substantial back payments of annual charges. In addition, if unlawful construction of projects is the majority's concern, the Commission has ample authority to enjoin such violation of the Act under section 314(a) of the Federal Power Act of which the Commission's enforcement staff has availed itself in recent years. Clearly, the Commission is not defenseless and instead has developed a formidable arsenal of procedural weaponry to encourage unlicensed project owners to file for licenses if required by law.

In any event, the 1986 amendments to the Federal Power Act made by the Electric Consumers Protection Act (ECPA) *do not* in any substantive way address unlicensed hydroelectric operation. Indeed, the House Report which is so enthusiastically embraced as justification for the majority's decision, refers to unlicensed operation as an "alleged problem." The House Committee Report *does not* recommend or even suggest that the Commission must or should apply civil penalties to unlicensed hydroelectric projects. Instead the House Report merely opines that it expects the Commission to locate projects that are being operated without legal authority and to enforce the law, and directs the Commission to make a "report to the Committee within six months about this *alleged problem*." (Emphasis added.) It is hard to fathom that Congress would have prescribed such a punitive measure without some specific discussion as to why it is necessary, particularly in light of the House Committee's request to obtain further information in the form of a Commission Report on the "alleged problem." I for one have never seen the report, and in any event, if Staff did send such a report, Congress has not seen fit to act or acknowledge a need for the Commission to act.

At the November 16, 1988, Commission Meeting, all of my colleagues agreed that the imposition of civil penalties of $10,000 a day with possibly retroactive effect to October 16, 1986, the date ECPA became law, is an extraordinary measure with serious due process implications. Yet, without any hard evidence that extraordinary measures are needed, the majority has adopted a flawed interpretation of section 31 of the FPA that will have the effect of chilling efforts to legitimately offer counter arguments to Commission determinations of jurisdiction. I submit that such an effect is clearly not in the public interest.

This persuades me that the more rational approach is to continue with the procedures already in place for dealing with unlicensed projects which have been effectively implemented for many years. By staying this course, we will be able to perform our responsibilities and, at the same time, abandon the strained interpretation of section 31 that will unnecessarily and illegally permit the Commission to use civil penalties as a cudgel to coerce unlicensed projects to accept Commission determinations of jurisdiction.

Charles A. Trabandt,

Commissioner.

[FR Doc. 88–29108 Filed 12–16–88; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committees

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its advisory committee regulations to provide that, when a member of the uniformed services, including a member of the Commissioned Corps of the Public Health Service, is appointed to serve on an advisory committee, he or she is not appointed as a special Government employee. Rather, the person's advisory committee duties would be regarded as part of the person's assigned functions as a member of the Commissioned Corps or other service.

EFFECTIVE DATE: December 19, 1988.

FOR FURTHER INFORMATION CONTACT: Richard L. Schmidt, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: With some exceptions, existing regulations provide that persons selected to serve on FDA's advisory committees are appointed as special Government employees. In staffing its advisory committees, FDA sometimes wishes to select appropriately qualified persons who are members of the uniformed services, including the Commissioned Corps of the Public Health Service. However, an obstacle to this course of action is that members of the uniformed services may not hold dual Government appointments. Accordingly, FDA is amending its regulations to provide that, when members of the Commissioned Corp or other uniformed services serve on FDA's advisory committees, they do so as part of their assigned functions in the Federal Government or the Commissioned Corps or other service, without appointment as special Government employees.

Because this rule relates to agency management and personnel, it is exempt from the usual requirements of notice, public procedure, and delayed effective date. (See 5 U.S.C. 553(a)(2).)

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR Part 14 continues to read as follows:

Authority: 5 U.S.C. 5332 note; 15 U.S.C. 1451 et seq.; 21 U.S.C. 41 et. seq.; 141 et seq., 321–371, 467f(b), 679(b), 821, 1031 et seq.; 42 U.S.C. 201 et seq.; 257a; 21 CFR 5.10.

2. Section 14.80 is amended by revising paragraphs (a)(2) and (b)(l)(ii) to read as follows:

§ 14.80 Qualification for members of standing policy and technical advisory committees.

(a) * * *

(2) Are subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service (the Commissioner has determined that, because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing these interests, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services); and

* * * * *

(b) * * *

(l) * * *

(ii) Except for members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), are subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service.

* * * * *

3. Section 14.95 is amended by revising paragraph (a) to read as follows:

§ 14.95 Compensation of advisory committee members.

(a) (1) Except as provided in paragraphs (a) (2) and (3) of this section, all voting advisory committee members shall, and nonvoting members may, be appointed as special Government employees and receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(2) Members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) are not appointed as special Government employees. Any member of TEPRSSC who is not a Federal employee or member of the uniformed services, including the Commissioned Corps of the Public Health Service, shall receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(3) Voting and nonvoting advisory committee members who are members of the uniformed services, including the Commissioned Corps of the Public Health Service, provide service on Food and Drug Administration advisory committees as part of their assigned functions, are not appointed as special government employees, but are reimbursed by the Food and Drug Administration for travel expenses.

* * * * *

Dated: December 12, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–29029 Filed 12–16–88; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 14

Advisory Committees; Establishment and Termination

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of the Dental Products Panel and the termination of the Dental Devices Panel. This document revises the agency's list of standing advisory committees to show these actions.

EFFECTIVE DATE: December 19, 1988.

Authority for the Panel will remain in effect until amended or terminated by the Commissioner of Food and Drugs.

FOR FURTHER INFORMATION CONTACT: Richard L. Schmidt, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 and 21 CFR 14.40(b)), FDA announces the establishment of the Dental Products Panel (the Panel). The Panel will review and evaluate available data concerning the safety and effectiveness of dental devices currently in use and advise the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification of these devices into one of three regulatory categories: Class I (general controls), class II (performance standards), or class III (premarket approval); recommend the assignment of a priority for the application of

regulatory requirements for devices classified in the standards or premarket approval category, advise on any possible risks to health associated with the use of devices; advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category; review classification as appropriate; recommend exemptions to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act; advise on the necessity to ban a device; and respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

The Panel also will function at times as an over-the-counter (OTC) drug advisory panel. As such, the Panel will review and evaluate data concerning the safety and effectiveness of active ingredients, and combinations thereof, of various currently marketed nonprescription drug products for human use and the adequacy of their labeling, and will advise the Commissioner on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded. The Panel will evaluate data and make recommendations concerning the approval of new drug products for human use and whether various prescription drug products should be changed to OTC status.

Because this is a technical amendment to Part 14, the Commissioner finds under 21 CFR 10.40(c), (d), and (e) that notice, public procedure, and delayed effective date are unnecessary and contrary to the public interest.

Concurrently with the establishment of this Panel, the Commissioner terminated the Dental Devices Panel.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR Part 14 continues to read as follows:

Authority: 5 U.S.C. 5332 note; 15 U.S.C. 1451 et seq.; 21 U.S.C. 41 et. seq.; 141 et seq., 321–371, 467f(b), 679(b), 821, 1031 et seq.; 42 U.S.C. 201 et seq.; 257a; 21 CFR 5.10.

2. Section 14.100 is amended by revising paragraph (d)(1)(iv) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(d) * * *

(1) * * *

(iv) *Dental Products Panel.* (*a*) Established March 5, 1988.

(*b*) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation. Reviews and evaluates data concerning the safety and effectiveness of over-the-counter (OTC) drug products for human use and makes appropriate recommendations to the Commissioner.

* * * * *

Dated: December 13, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–29049 Filed 12–16–88; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 176

[Docket No. 85F–0427]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of the copolymer of acrylic acid and 2-acrylamido-2-Methylpropanesulfonic acid, including its ammonium/alkali metal mixed salts, as a scale inhibitor in the manufacture of paper and paperboard intended for use in contact with food. This action responds to a petition filed by Calgon Corp.

DATES: Effective December 19, 1988; written objections and requests for a hearing by January 18, 1989.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 17, 1985 (50 FR 42095), FDA announced that a petition (FAP 5B3886) had been filed by Calgon Corp., Pittsburgh, PA 15230, proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of the copolymer of acrylic acid and 2-acrylamido-2-methylpropanesulfonic acid as a scale inhibitor in the manufacture of paper and paperboard in contact with food. Subsequently, in a notice published in the **Federal Register** of August 19, 1986 (51 FR 29612), FDA announced that the filing of the petition by Calgon Corp. had been amended to include the use of ammonium/alkali metal mixed salts of the copolymer in addition to the acid form of the copolymer.

FDA has reviewed the safety of both the additive and the starting materials used to manufacture the additive as well as the byproducts associated with the manufacturing process. Although the additive itself has not been found to cause cancer, it has been found to contain minute amounts of unreacted acrylonitrile monomer (a carcinogenic reactant used in the manufacture of the additive). Residual amounts of reactants and manufacturing aids, such as acrylonitrile monomer, are commonly found as contaminants in chemical products including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d Sess. 4 (1958).) This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve a use of an additive that contained or was suspected of